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## The Limits of Product Liability Reform within a Consumer Expectation Model: A Comparison of Approaches Taken by the United States and the European Union

John G. Culhane

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# The Limits of Product Liability Reform Within a Consumer Expectation Model: A Comparison of Approaches Taken by the United States and the European Union

By JOHN G. CULHANE\*

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## I. Introduction

For more than a decade, the pace of product liability legislation in the United States and in Europe has been brisk. Domestically, the

Model Uniform Product Liability Act (MUPLA or the Act),<sup>1</sup> as adopted in some form by many states,<sup>2</sup> has been the principal engine of change. The European Union's surprisingly parallel approach is captured by the Product Liability Directive (the Directive), brought into effect by national legislation in the member states.<sup>3</sup>

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1. MODEL UNIFORM PRODUCT LIABILITY ACT (1979) [hereinafter MUPLA]. MUPLA has been selected over its principal competition, the proposed revision of the Restatement (Second) of Torts § 402A, which is slated to find its way into a Restatement (Third) of Torts. For an exhaustive discussion of the proposed Restatement (Third) of Torts: Products Liability, see Symposium, *A Symposium on the ALI's Proposed Restatement (Third) of Torts: Product Liability*, 61 TENN. L. REV. 1043-1454 (1994). My reasons for selecting MUPLA over competing legislation and proposals are three: First, MUPLA has been in place for more than a decade now, and many of its provisions have found their way into the legislation of specific states. Second, it represents a more detailed and therefore more useful document, and expressly incorporates procedural reform, which the Restatement proudly eschews. Finally, valid questions have been raised about whether the proposed Restatement of Product Liability is even deserving of the name. As Professor Little has pointed out, the drafters of the Restatement, in attempting to define design defect, have "abandoned this orthodox [r]estatement approach [and have instead] essentially sought to limit design defect liability to cases involving proof of safer alternative designs." Joseph W. Little, *The Place of Consumer Expectations in Product Strict Liability Actions for Defectively Designed Products*, 61 TENN. L. REV. 1189, 1193 (1994). The full text of MUPLA is reprinted in RICHARD F. SCHADEN & VICTORIA C. HELDMAN, *PRODUCT DESIGN LIABILITY*, APP. A (1988).

2. By one count, thirty-eight states have enacted some legislation bearing on product liability. These statutes have been collected and exhibit such rich variety that they are beyond summary here. *Prod. Liab. Rep. (CCH)* vol. 2. MUPLA has been selected for analysis because it represents a fair cross section of the reform statutes. By way of example, states have: (1) limited the liability of nonmanufacturing sellers, *see, e.g.*, COLO. REV. STAT. ANN. § 13-21-402 (West 1989); GA. CODE ANN. § 51-1-11.1 (1990); IDAHO CODE § 6-1407 (1989); ILL. ANN. STAT. ch. 110, para. 2-621 (Smith-Hurd Supp. 1990); IOWA CODE ANN. § 613.18 (West Supp. 1990); KAN. STAT. ANN. § 60-3306 (1994); KY. REV. STAT. ANN. § 411.340 (Michie/Bobbs-Merrill Supp. 1990); MD. CODE ANN., 0 [CTS. & JUD. PROC.] § 5-311 (1984); MINN. STAT. ANN. § 544.41 (West 1990); MO. ANN. STAT. § 537.762 (Vernon 1988); N.C. GEN. STAT. § 99 B-2 (1994); OHIO REV. CODE ANN. § 2307.78 (Baldwin Supp. 1989); TENN. CODE ANN. § 29-28-106 (Supp. 1994); (2) expressly permitted manufacturers to escape liability by proving that their product was the "state of the art" at the time of its manufacture; and (3) have disallowed recovery for products that were modified after leaving the manufacturer, either by third parties or by the plaintiff. *See* James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1529 n.17 (1992). State laws also pose a host of procedural hurdles for product-injured plaintiffs to vault before reaching recovery. Common examples include statutes of limitation and repose, and modifications to the rules of joint and several liability. Many of these provisions take their cue from MUPLA. *See* discussion *infra* Part IV.

3. Council Directive 85/374 of 25 July 1985 on the approximation of the laws, regulations, and administrative provisions of the member states concerning liability for defective products, 1985 O.J. (L 210) 29 [hereinafter Directive]. A complete listing of the implementing statutes with effective dates is set forth, *infra*, n.137.

The similarities between the approaches extend to both underlying philosophy and implementation. First, both MUPLA and the Directive largely follow the civil law's tradition of attempting to blanket a field through legislation so as to streamline, unify, and to some extent dictate the ensuing decisional law. Because of its obvious appeal, this approach claims a number of adherents among those schooled in the common-law tradition as well.<sup>4</sup> Second, both legislative initiatives impose strict liability for injury caused by defective products,<sup>5</sup> but then hedge that basic principle with significant limitations.<sup>6</sup> Both also impose statutes of repose,<sup>7</sup> restrict the liability of nonmanufacturing sellers,<sup>8</sup> and recognize compliance with "state of the art" (or, as the Directive has it, "development risks") as a complete defense.<sup>9</sup>

Although the statutes bear substantial similarities, it would be a mistake to assume that these responses to the problems of defective products have evolved from similar backgrounds. As has been emphasized in the zeal for reform currently barreling through the United States Congress, the domestic movement has largely been a response to the perceived excessive costs of product liability litigation, with its supposed attendant effects on the ability of corporations to produce useful products and to compete in increasingly global markets. The Directive, on the other hand, was animated by the perception that member states' existing product liability law was unfair to consumers and generally unfavorable to product liability plaintiffs.

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4. This impulse among common-law scholars often finds voice in the demand for "fixed rules of tort liability." Richard A. Epstein, *The Risks of Risk/Utility*, 48 OHIO ST. L.J. 469, 469 (1987).

5. Directive, *supra* note 3, art. 1 (*see infra* subparts III.B.1 & 2); MUPLA, *supra* note 1, § 104 (*see infra* subpart IV.B.1(a)).

6. These restrictions begin with the very definition of defect. *See* MUPLA, *supra* note 1, § 104 (B)(1); Directive, *supra* note 3, art. 6. For a detailed discussion of other limitations on liability, *see infra* subpart III.B (discussing the Directive) and subpart IV.B (discussing MUPLA).

7. Directive, *supra* note 3, art. 11 (imposing an absolute limit of "10 years from the date on which the producer put into circulation the actual product which caused the damage"); MUPLA, *supra* note 1, § 110 (creating a presumption rebuttable by clear and convincing evidence).

8. Directive, *supra* note 3, art. 3, § 3 (exculpating nonmanufacturing "suppliers" who "inform . . . the injured person . . . of the identity of the producer or of the person who supplied him with the product"); MUPLA, *supra* note 1, § 105 (allowing exculpation of faultless nonmanufacturing sellers unless manufacturer is unavailable).

9. Directive, *supra* note 3, art. 7, § e (defense that state of current scientific and technological development was such that the defect could not have been discovered); MUPLA, *supra* note 1, § 107(D) (product seller not liable if it can prove that "it was not within practical technological feasibility to make the product safer"). By the terms of Article 15, member states are permitted to derogate from the Directive's state of the art defense.

These parallel projects in product liability law are significant and will continue to have importance. An understanding of the history of each undertaking can inform scholarly efforts and judicial decisions in the field of products liability. Through a critical, narrative style, this Article assays an historically grounded comparison of the two statutory approaches and offers observations as to the nature of product liability law and the requirements of justice that bear on all reform proposals.

In searching out the requirements of justice, this Article argues for two central truths about product liability. These truths, once recognized, can remove much of the mystery currently enshrouding virtually every area of product defect adjudication. The first of these is that legislation should generally be limited to issues concerning the conduct of litigation. As to such issues, legislative oversight can impart a welcome consistency and achieve a considered balance that is fair to injured consumers and which also discourages unnecessarily burdensome litigation. As to substantive issues, however, *ex ante* regulation is a mistake, especially if the legislation has dispositive effect. Questions such as whether a product is defective, and whether or to what extent the manufacturer should be liable for a particular "development risk," should be answered by the courts, operating with the benefit of a full factual record. Otherwise, substantive definitions and rules leech from courts the flexibility and attention to factual nuance that are peculiarly within their judicial competence.<sup>10</sup>

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10. This position may appear contradictory to that espoused by Professor Henderson, who has argued that issues of product design are polycentric and therefore beyond the institutional competence of courts: "[P]olycentric problems are many-centered problems, in which each point for decision is related to all the others as are the strands of a spider web. If one strand is pulled, a complex pattern of readjustments will occur throughout the entire web . . . . Because absolute [product] safety is not attainable . . . the engineer must place relative values upon a multitude of factors. The decisions he must make regarding these factors are as interrelated and interdependent as the strands of an intricate web." James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1536, 1540 (1973).

Ultimately, Professor Henderson's argument against judicial intervention in design defect cases is less absolute than it first appears. For one thing, he is careful to distinguish inadvertent design errors from conscious design choices, *id.* at 1547-50, and acknowledges that the availability of an external engineering standard in cases of inadvertence makes such cases amenable to judicial resolution. Many of the examples adduced throughout this Article, and where I argue that liability should attach, involve such inadvertent errors in design. In such cases, as Henderson also notes, the peril is likely to be concealed from the product user, and would therefore betray the consumer's expectation. *Id.* at 1549. Second, Professor Henderson recognizes that cases involving bystanders, or in which there is a readily available market alternative that other manufacturers are using, have properly resulted in judicial regulation. *Id.* at 1565-73. Yet in the former class of cases there is no

The argument that courts must assume the primary role in product liability grows out of the second "truth" that informs this Article: analysis should focus on a product's marketing and representation, and on the consumer expectation that such salesmanship creates. Such a focus will develop naturally during the course of the adjudicative process and will allow consideration of a number of case-specific issues: how the product was marketed; how well the consumer understood (or could have understood) any dangers it presented; whether an alleged product misuse was one that the seller either could have expected or actively encouraged; the alternatives available to the manufacturer at the time of distribution and the costs of those alternatives; the setting in which the injury occurred; and the kind of presale scrutiny—by the manufacturer, the industry, and the regulators—to which the product was subjected. It should be conscripted that these questions, even those that seem outside the scope of consumer expectation, should be adapted to the task of assessing those expectations.<sup>11</sup>

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particular reason to believe that the problems of polycentricity can be avoided. Third, his position leads him to champion liability for failure to warn, since warnings are the way to tell the consumer about the risks that the manufacturer has chosen to impose. *Id.* at 1558-65. But the issues of which warnings to impose, and how such warnings are best communicated, involve their own problems of polycentricity. Henderson tries to avoid these by "assum[ing] that . . . courts will commit themselves to a rule of full disclosure regardless of what might be described as indirect or secondary costs or consequences of such disclosure." *Id.* at 1559-60 n.121. This assumption is naive, as the events of the past twenty years have borne out. In fact, courts have been impelled to recognize that full disclosure is undesirable, if not impossible. *See, e.g.,* *Liesener v. Weslo, Inc.*, 775 F. Supp. 857, 861 (D. Md. 1991) ("the manufacturer need not warn of every mishap or source of injury that the mind can imagine flowing from the product"); *Cotton v. Buckeye Gas Prod. Co.*, 840 F.2d 935, 938 (D.C. Cir. 1988) (noting the time and effort needed to grasp each warning, the court states that "[t]he inclusion of each extra item dilutes the punch of every other item. Given short attention spans, items crowd each other out.").

Perhaps most importantly, Professor Henderson's admonition to courts to not exceed their institutional competence rests on the assumption that regulatory, and to a lesser extent, industry-imposed standards will achieve the proper market balance between safety and risk. Henderson, *supra*, at 1555-57 ("governmental bodies . . . are presumed to be free from partiality or abuse."). As I demonstrate in subpart IV.B.1(c), *infra*, such an assumption cannot be supported by the facts, even as to "impartial" regulators. A fortiori, interested industry standards should be afforded little weight. He does acknowledge that regulatory and market failures will induce courts to adjudicate polycentric problems. Henderson, *supra*, at 1578. I agree that regulatory efforts to create safe products are preferable to judicial resolution, especially since well-engineered products will not injure consumers in the first place. But, problems of polycentricity notwithstanding, courts cannot and should not abdicate their responsibility to redress injury.

11. This approach borrows from that taken by Professor Marshall Shapo in his influential work, *A Representational Theory of Consumer Protection: Doctrine, Function, and Legal Liability for Product Disappointment*, 60 VA. L. REV. 1109 (1974). His thesis is that "[j]udgments of liability for consumer product disappointment should center initially and

This representation-based, consumer expectation approach to the law of defective products is a logical outgrowth of the position espoused as long ago as Justice Traynor's landmark 1944 concurrence in *Escola v. Coca Cola Bottling Co.*<sup>12</sup> Where the consumer has no means of self-protection, strict liability places responsibility for injury-causing defects upon the manufacturer, because it is best-positioned to prevent the defect and can usually spread the costs of any injuries that do occur. Of course, the considerations set forth above recognize that in many cases, the course of communication between manufacturer and seller is more involved than that of the paradigm latent manufacturing defect situation, where the consumer's helplessness is total.<sup>13</sup> Those more complex cases, which now dominate the law of product liability, cannot be decided absent the full-throated factual development that is the special genius of the common law.

For the most part, this argument is developed incrementally, through critical comparison of the Directive and MUPLA and through the product-category analyses that follow.<sup>14</sup> I hope this approach allows the Article's narrative structure to develop naturally, and that this "prescription in action" approach not only suits the comparative nature of this piece, but will also fill a need, since thoughtful and well-grounded pieces on what might be deemed "first principles"

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principally on the portrayal of the product which is made . . . by the seller. This portrayal should be viewed in the context of the impression reasonably received by the consumer from representations or other communications made to him about the product." *Id.* at 1370. Yet, in setting forth the "[c]onsiderations relevant to decisionmaking on the basis of this model," *id.*, he includes such consumer-independent factors as "[t]he incentives that the proposed decision would provide to make the product safer, [and] the likely effects on prices and quantities of goods [and services]." *Id.* at 1371.

12. 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).

13. A necessary corollary of this position is that liability should also attach even where the product's dangers were unknowable at the time of sale. This view has been forcefully presented in the recent article by Mark McLaughlin Hager, *Don't Say I Didn't Warn You (Even Though I Didn't): Why the Pro-Defendant Consensus on Warning Law is Wrong*, 61 TENN. L. REV. 1125 (1994). As he notes, few decisions have gone this far. *Id.* at 1120 n.32 (citations omitted). The question of the proper course of communications for cases involving unknowable defects is addressed *infra* in subpart V.D. However, where no information is provided to those who are exposed to dangerous products—as was so in the asbestos cases—liability should be (as it sometimes has been) strict. *Id.* See also Little, *supra* note 1, at 1193-94 (criticizing the proposed Restatement's retooling of the design defect standard by noting that it "simply and neatly eliminates the concept of strict liability from product design law. Gone is the notion that where a product is determined . . . to be unreasonably dangerous . . . a seller places such a product in the market at the seller's peril.").

14. This latter approach has recently been taken by Marshall S. Shapo in MARSHALL S. SHAPO, *PRODUCTS LIABILITY AND THE SEARCH FOR JUSTICE* (1993). See *id.* at 4 (explaining his case study methodology).



of product liability are already available.<sup>15</sup> In making this case, I take a somewhat unusual approach. The Article begins with a brief discussion of law-making in civil-law jurisdictions before the enactment of the Directive. Part II is meant to serve two purposes. First, within the specific context of product liability, an overview of the pre-Directive law shows the emergence of the Directive from a background comparatively unfavorable to consumers. The second aspect of this discussion is a more general consideration of the relation between the legislature and judiciary within the civil-law context. The dramatic gulf between the "folklore" of this relation and its practice illustrates the danger of exhaustive legislative regulation, particularly in a rapidly changing area of law.

In Part III, I analyze the European Union's Product Liability Directive. This discussion is preceded by a brief history of the process of directive promulgation in general and of the Product Liability Directive in particular. Only thereby can the reader appreciate the limitations that have compromised the Directive's promise from the start.

Part IV is something of a parallel exercise applied to the domestic experience of product liability reform under MUPLA and consistent state statutory reforms. Again, this discussion is energized by a brief historical overview of the development of the product liability law that has spawned such reform. Parts III and IV are largely exegetical, intended to set the stage for Part V's critical assessment of the wisdom of legislative responses to the problems of product injuries and product litigation.

The mixed assessment rendered in Part V is developed by considering categories of products that either make for good paradigms (such as manufacturing defects and crashworthiness problems) or that raise issues that have often been considered unique (e.g., workplace injuries and sale of pharmaceuticals). For each class of products, the Article works through a series of cases—real and hypothetical—for

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15. See, e.g., David G. Owen, *The Moral Foundations of Products Liability Law: Toward First Principles*, 68 NOTRE DAME L. REV. 427 (1993). Professor Owen's piece, and the seminal work by Professor Shapo which constitutes an effective empirical brief on behalf of the consumer expectation test, Shapo, *supra* note 11, are the principal inspirations for the normative conclusions drawn throughout this Article. See also John B. Attanasio, *The Principle of Aggregate Autonomy and the Calabresian Approach to Products Liability*, 74 VA. L. REV. 677 (1988); Alan Schwartz, *The Case Against Strict Liability*, 60 FORDHAM L. REV. 819 (1992); Alan Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis*, 97 YALE L.J. 353 (1988). As Professor Owen noted, the weakness and the strength of the three articles just cited are the same: "[By] organizing products liability law around a single moral pole, [they exclude] from consideration other perspectives . . . ." Owen, *supra*, at 433.

the purpose of demonstrating both the likely practical effect of the reform provisions and the extent to which the consumer's expectation is or is not sufficiently valued by these competing regimes.

We begin with a compelling object lesson on the danger of over-regulation.

## II. Civil Law Treatment of the Law of Defective Products

The commentary on the Directive typically discusses the state of product liability law before its effective date,<sup>16</sup> and may also pause to consider the Directive's elliptical path toward approval by the European Community,<sup>17</sup> before analyzing the language and implications of the Directive itself. An effort to more broadly embed the discussion within the civil-law tradition is seldom seen.<sup>18</sup> I now proceed to do so, not primarily for reasons of historical interest, but in order to highlight some aspects of civil law that may be instructive in settling on a proper hermeneutic and assessment of reform legislation.

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16. Two comprehensive books that focus on the Directive also discuss some of the preexisting law. See CHRISTOPHER HODGES, *PRODUCT LIABILITY: EUROPEAN LAWS AND PRACTICE* 3-8 (1993); GERAINT HOWELLS, *COMPARATIVE PRODUCT LIABILITY*, chs. 3-4 (United Kingdom), 7 (France), and 8 (Germany) (1993). See also Frank A. Orban III, *Product Liability: A Comparative Legal Restatement—Foreign National Law and the EC Directive*, 8 GA. J. INT'L & COMP. L. 342 (1978); Kathleen M. Nilles, Note, *Defining the Limits of Liability: A Legal and Political Analysis of the European Community Products Liability Directive*, 25 VA. J. INT'L L. 729, 732-40 (1985); Donna Shettler, Note, *Products Liability: A Comparison of U.S. and EEC Approaches*, 13 SYRACUSE J. INT'L L. & COM. 155 (1986).

17. See, e.g., Lori M. Linger, *The Products Liability Directive: A Mandatory Development Risks Defense*, 14 FORDHAM INT'L L. J. 478, 479-83 (1990); Nilles, *supra* note 16, at 748-56. The entity that promulgated the Directive was the European Community and is now called the European Union. This name change was accomplished at a meeting of members in Maastricht, the Netherlands, on Dec. 9-10, 1991. *Id.*

18. There is at least one good reason for this, namely, not all of the nations that form the Union have a civil-law tradition. This Article omits the product liability experience in Great Britain for two reasons. First, to the extent that product liability law reflects common-law development, the United States experience, discussed in Part IV, *infra*, is of more immediate interest; and second, searching analyses of pre-Directive product liability common law has already been accomplished. See HOWELLS, *supra* note 16, at 51-83. For a spirited discussion of the effect of European unification on the British common law more generally, see Colloquy, *Can the Common Law of the United Kingdom Survive European Unification?*, 22 IDEA J. L. & TECH. 171 (1992).

### A. *Civil Law: Doctrine, Law, and Interpretation*<sup>19</sup>

The syntax of the civil law is foreign to a common law lawyer. At the risk of gross overgeneralization, the formal sources of the civil law begin and end with the legislature: thus, constitutional law;<sup>20</sup> national, regional, and local legislation; and implementing regulations, constitute the binding or "written" law. For reasons that are largely historical, "custom"<sup>21</sup> is sometimes considered another source of law. Conspicuously lacking is judicial precedent, which historically has not been regarded as binding.<sup>22</sup> As we will see, this notion of the second-class treatment of decisional law is to some extent a matter of folklore, not of reality. Nonetheless, the implications of the stated hierarchy have profoundly affected juridical business in civil-law countries. These same implications can serve as a warning against taking too seriously the notion of legislative supremacy—an admonition perhaps especially apt in the product liability field.

#### 1. *Historical Sources of the Civil Law*

How did the civil law come to the position, curious from a common lawyer's perspective, that judicial decisions are without precedential value? This question cannot be approached without some basic understanding of the civil law's roots in Roman law.

In the late days of the fracturing Roman Empire, the Byzantine Emperor Justinian commissioned a number of scholars to undertake a codification, of sorts, of the "best" Roman law that could be found. Their product, now referred to as the *Corpus Juris* of Justinian, or simply as the Justinian Code, contained a number of sections, most notably the *Digests*, which were summaries of decided cases; and the *Institutes*, which made the *Corpus Juris* intelligible by "set[ting] out

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19. I have borrowed this heading from Merryman's important three-part article on the Italian legal system; his categories seem to me instructive in attempting to understand the workings of the civil law. John Henry Merryman, *The Italian Style I: Doctrine, The Italian Style II: Law, The Italian Style III: Interpretation*, 18 STAN. L. REV. 39-65, 396-437, 583-611 (1965-66) [hereinafter Merryman, *Doctrine*; Merryman, *Law*; and Merryman, *Interpretation* respectively].

20. Not all civil-law jurisdictions have a formal, written constitution.

21. The meaning of "custom," and how it is pressed into service in the various civil law countries, could be the subject of a treatise. One coherent explanation appears in JOHN P. DAWSON, *THE ORACLES OF THE LAW* 417-24 (France), 440-45 (Germany) (1968).

22. See Merryman, *Law*, *supra* note 19, at 398. It can be argued that this statement is somewhat out of date. If the jurisdiction in question has a constitutional court, for example, that court's interpretation of the constitutionality of a legislative enactment bind both the legislature, and in turn, subsequent courts. *Id.* at 400-01.

the elementary principles of the law in remarkably perspicuous order."<sup>23</sup>

Owing to a dearth of original source material, it is difficult to know how accurately the *Corpus Juris* captured the spirit of the cases it summarized.<sup>24</sup> What is clear is that the Digests were highly abstract, formalistic statements of authority—not too different from how one imagines a digest today. As Professor Dawson has pointed out, the Digests are riddled with maxims, inferred by the compilers from the original decisions, and stated in a form suggestive of sovereign ukase. These pronouncements, thought to flow from the ruler, were considered the only true source of law.<sup>25</sup>

Dawson can therefore state accurately that "[j]udicial decisions were merely examples"<sup>26</sup> of the operation of legal principles. Thus was born the tenet, waning today in the civil law, that decisional law was without binding effect.<sup>27</sup> Of course, the locus of official power has since shifted from the sovereign to the legislature, but that change has not improved the formal status of the judiciary.

The subsidiary position of the judiciary was reinforced from the early twelfth century by the Glossators, legal scholars who resurrected the *Corpus Juris* and then began an exhaustive process of exegesis. At least initially, the Glossators did not critically examine whether the positive law found in the *Corpus* was sound; as subjects of the much-transformed Roman Empire, they accepted that they and all citizens were still bound to follow its pronouncements.<sup>28</sup>

The effect of their exegesis, however, was to belie this cardinal principle of sovereign supremacy. Any text examined as microscopically as was the *Corpus Juris* was bound to acquire an interpretive gloss that somewhat supplants the studied document itself.<sup>29</sup> The

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23. Lecture Delivered at the University of Michigan (Nov. 16, 1953) in F.H. LAWSON, *A COMMON LAWYER LOOKS AT THE CIVIL LAW* 10 (1955).

24. It has been suggested that the Digests were inaccurate in this respect. See LAWSON, *supra* note 21, at 122-24.

25. *Id.*

26. *Id.* at 123.

27. See LAWSON, *supra* note 23, at 82 ("The . . . distinction, between a Common Law made by judges and a Civil Law made by jurists, has long been wearing thin."). Professor Lawson then moves on to a discussion of the role of precedent in France, Germany, and Italy, *id.* at 83-86, and concludes that its "force . . . is pretty clearly greatest in France and much less in Italy, which has a [then] recent civil code." *Id.* at 86.

28. See *id.* at 22-23. See also LAWSON, *supra* note 21, at 127 (the Glossators "[a]ccept[ed] the value of the whole and of every part.").

29. Professor Dawson makes this point graphically, in discussing the Glossators' treatment of local custom, specifically acknowledged as a source of law in the Digests, but often

Glossator scholars thus developed a growing reputation as oracles of the law. The interesting result, which yet echoes throughout the civil law, is a curious assignment of roles: the sovereign—today the legislature—is the sole creator of law, but requires the services of the legal academy to interpret that law. The judge is assigned the lesser role of application. He or she is the engineer, the applied scientist who is called upon to follow the text, gratefully accepting guidance from scholars who have made a career of studying legal text.<sup>30</sup>

Over the course of centuries, this reinvigorated Roman law migrated throughout Western Europe. The Roman law was “received” in certain places; that is, it became the law of a particular area. This was certainly true in Italy,<sup>31</sup> and there is some support for the view that the same happened in Germany.<sup>32</sup> In France, the Roman law played a more significant role in some areas than in others.<sup>33</sup> Even where Roman law was received, however, it naturally accepted scions of local customary law.

Local law thus became a hybrid of sorts. Local customs and mores somewhat transformed the received Roman law, while still retaining a common, Roman root. Therefore, when emerging nation-states such as France, Italy, and Germany undertook to codify their laws during the eighteenth century, the animating principles of the *Corpus Juris* survived. For present purposes, the most important principles concern the relationships between the legislature, the courts, and the legal academy.

France provides the best illustration of how the impulse toward codification of Roman law dovetailed with contemporary political ideology. The French Civil Code, or Code Napoleon, which became effective in 1804, reflects both substantive Roman law and its underlying assumptions. On a substantive level, the French Civil Code reflects basic Roman law precepts of freedom of contract and the preemi-

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in real or apparent opposition to express commands of the *Corpus Juris*. DAWSON, *supra* note 21, at 128-34.

30. “[T]he . . . judge [is relegated] to inferior status, as the operator of a machine designed and built by scholars and legislators . . . . The tendency is to think of a judge as just another kind of civil servant. Judicial appointment is not a reward for distinguished academic or government service or for eminence in practice, it is not the crowning achievement, the ultimate recognition, that it often is in the common-law world.” Merryman, *Interpretation*, *supra* note 19, at 589 (speaking particularly of the Italian experience).

31. DAWSON, *supra* note 21, at 125-26.

32. As Professor Dawson has pointed out, there is wide disagreement among German scholars regarding the extent to which Roman law influenced German law; indeed, two camps have formed over the issue (“Germanists” and “Romanists”). *Id.* at 176-85.

33. *Id.* at 263-66.

nence of private property rights. These concepts served France as well as they had served the Rome of the Republican epoch. The bourgeoisie that arose after the French Revolution demanded, and won, protection of those rights most central to those with money but without royal blood.<sup>34</sup>

Further, the distrust of the king and of the parlements or royal courts that were in his thrall found natural expression in the doctrine of legislative supremacy. The legislature, as a democratically chosen body, was to "speak the law." That task was not to be entrusted to the judiciary.<sup>35</sup>

One might therefore expect to find a highly detailed Code, one that could supply solutions to every legal problem in advance. In fact, the Code Napoleon is written in rather general terms. It is fiction to state that a judge will invariably be able to discern the answer to a particular legal problem by consulting the Code.<sup>36</sup> Consistent with the Roman law interpretation, the scholar soon began to fill that void between written law and the judicial task of interpretation. It might even be said that the legal academy, practically moribund in 1804, was reanimated precisely by the perceived need for such interpretation as well as by the Code itself.<sup>37</sup> Despite Napoleon's celebrated objection to any interpretation of his Code,<sup>38</sup> the reemergent scholar served the national interest, at least in theory, by devising "correct" interpretations of the various provisions of the Code. Those interpretations, in a sense part of the Code itself, were to supply any guidance the judiciary might need when the language of the Code did not unequivocally determine the resolution of a case.<sup>39</sup> The Glossators had reemerged, in different garb.

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34. *Id.* at 382-86.

35. *Id.* at 403-05.

36. Indeed, Dawson has noted that the courts were called upon to "fill the great empty spaces around the high superstructure of the Civil Code." *Id.* at 283.

37. *Id.* at 387.

38. Upon learning that the Code had been the subject of interpretation, Napoleon is reported to have said: "My Code is lost." *Id.* at 287 n.5 (citing GAUDEMET, BASLER STUDIEN, Vol. 8, 13).

39. *Id.* at 392-94 (noting that the great exegeses began in the 1830's). Dawson has also noted that relying on the scholar to defend the Code, and more generally the notion of legislative supremacy, against all challengers eventually led to an unhappy solipsism. If one's own interpretation of the Code was "correct," then by hypothesis competing interpretations were "wrong." Each scholar thereby becomes the sole oracle of truth. *Id.* at 395-96.

## 2. *Current Approaches to Doctrine, Law, and Interpretation*

This conception of the workings of law in Code jurisdictions still directs at least the formal business of the law. Thus, in France as well as in Italy,<sup>40</sup> even the pronouncements of the supreme civil court are not binding on lower courts in subsequent cases, no matter how similar the facts might be.<sup>41</sup> This result follows inexorably from the tenet that only the legislature can make law; the courts just decide *this* dispute between *these* parties.

Furthermore, in France and in Italy the decisions by the courts are in much the same inscrutable form as the Digests of the Corpus Juris. In France, a decision is presented in the form of a logical syllogism in which a series of non-fact-specific "whereas" clauses are followed by a "therefore" statement.<sup>42</sup> Italian decisions are hardly more illuminating.<sup>43</sup> In a sense, the decisions in both France and Italy look oddly like legislation. Again, it is largely left to the legal academy, with some help from the practitioner, to organize and to interpret these decisions so as to provide the guidance that litigants and courts in fact need.

Germany's experience has been different. Interest in codifying German law flared shortly after the Code Napoleon was introduced, but the Germans took almost a full century to realize their goal of a civil code. The Code, enacted in 1896 and taking effect on January 1, 1900, achieved a legal synthesis and formal structure that remain impressive to this day.<sup>44</sup>

Despite its attempt at comprehensive regulation, the German Civil Code proved no more capable than its Italian or French counterparts of predicting future developments that might have evaded spe-

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40. The Italian Civil Code of 1865 was modelled closely on the Code Napoleon and shared many of its assumptions as well as its basic structure. The revised Italian Code of 1942 moves away from the highly individualized notions of private property and freedom of contract that were ascendant during the 19th century, and recognizes that other important societal goals dictate limitations of individual economic liberties. These broader goals are also reflected in the Italian Constitution, in effect since 1948. See Merryman, *Law*, *supra* note 19, at 408-17.

41. Indeed, the decision by the French Cour de Cassation is not binding even on the parties to the particular dispute before it; the court "quashes" (*casse*) the lower court's decree, and remands the case to another lower court for disposition. Only after a second hearing by the Cour de Cassation is the lower court bound to follow the Cassation's decree. Dawson, *supra* note 21, at 377-79.

42. *Id.* at 407.

43. Merryman, *Interpretation*, *supra* note 19, at 587.

44. For an illuminating discussion of these points, see Dawson, *supra* note 21, at 450-61.

cific codal regulation, and that would therefore require substantial judicial creativity. Fortunately, the Code contained a number of more general clauses, the plasticity of which allowed courts a measure of regulatory power. Two examples of judicial willingness to regulate will suffice.

The Industrial Revolution was in full swing by 1896, but the labor movement did not attract substantial judicial attention until shortly thereafter. Once claims began to be brought for what we might call unfair labor practices, the courts were placed in a difficult situation. The Code did not regulate labor matters. Therefore, the judiciary faced a dilemma: it could either be a party to injustice, by refusing to recognize that the complaining party had any rights—because no code section seemed to cover the issue—or it could “legislate” by using a more general provision to cover the conduct in issue.

The German court chose the latter approach. Section 826 of the Code “had not attracted much attention in the drafting process,”<sup>45</sup> but was retooled toward the development of labor regulation. The clause provides: “Whoever causes injury to another intentionally, in a manner offending good morals, is bound to repair the injury.”<sup>46</sup>

The “good morals” language soon acquired a judicial gloss that the drafters of the Code could not have predicted: “misuse of economic freedom through profit-seeking exploitation was proscribed.”<sup>47</sup> That interpretation was then quickly pressed into service in the developing struggle between labor and management, where section 826 grew into a blueprint for detailed regulation. A sprinkling of holdings illustrate this point: an employer could blacklist employees on strike during a wage dispute, but not a lone employee, and not without a strike; employee boycotts were permitted, but not if the employer was disproportionately weaker, and not without affording the employer fair notice and the chance to meet employee demands.<sup>48</sup>

A still more dramatic example of “the flight into the general clauses”<sup>49</sup> was the court’s treatment of section 242, which provides: “The obligor is bound to carry out his performance in the manner required by good faith with regard to prevailing usage.”<sup>50</sup> It was the

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45. *Id.* at 461.

46. *Id.*

47. *Id.* at 462.

48. *Id.* at 463-64.

49. *Id.* at 475. This phrase was coined by Justus W. Hedemann in JUSTUS W. HEDEMANN, *THE FLIGHT INTO THE GENERAL CLAUSES, A DANGER FOR LAW AND STATE* (1933).

50. DAWSON, *supra* note 21, at 461.



complete collapse of the German mark in the aftermath of World War I that triggered judicial resort to this very general language. The courts began rewriting contracts that had been entered into before the mark's decline, leaning heavily on the connected notions of "good faith" and the "tacit presumptions" underlying every consensual transaction.<sup>51</sup>

The court's bold initiatives in the restructuring of debt bear the earmarks of American judicial activism. The courts proclaimed themselves the equal of the legislature<sup>52</sup> and broadly stated that the codes were inherently incomplete.<sup>53</sup> The court also allowed the general terms of section 242 to override a subsequent, more specific piece of legislation that had seemingly precluded restructuring debt arising from an original money loan. Even riskier, the court admonished the legislature for considering legislation that would have expressly prohibited the judiciary from continuing to recast money debt as it had been doing: "The idea of good faith stands outside any particular statute or any particular provision of positive law . . . . Therefore the legislator may not . . . frustrate a result that good faith imperatively demands . . . ." <sup>54</sup>

The judiciary won the ensuing public relations battle, with the legislature acquiescing in the courts' continued restructuring of debt on a massive scale.<sup>55</sup> It is reasonable to suppose that the legislature came to believe in individualized solutions to the equitable problems of unwieldy debt structures, recognizing that legislative response would be too blunt an instrument. Not surprisingly, public approval of the judiciary's treatment of this difficult problem conferred great respect on the courts. Further, the German Legislature in the immediate post-World War I period was itself struggling for legitimacy to the extent that a partnership between the courts and the democratic lawmakers became necessary and evident.<sup>56</sup>

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51. *Id.* at 465-66.

52. "There are three sources by which private rights are created, the law of the parties (*i.e.*, the concurring wills of the parties, legislation and judicial law (*das richterliche Recht*)). The last of these stands fully equal in rank besides the other two . . ." *Id.* at 469 n.29 (citing *Juristische Wochenschrift* 910 (Third Senate, May 26, 1922)).

53. "[I]t is not enough to speak of a 'gap' in legislation, for this is to assume] that all the fullness and richness of life can be encompassed in a Code. That is impossible." *Id.*

54. *Id.* at 470.

55. In fixing a new value in particular cases, the court arrogated to itself the right to consider the entire financial condition of the parties to the contract. In so doing, the court was engaged in an *ad hoc* kind of redistribution of wealth. *Id.* at 471-72.

56. *Id.*

Thus, just as the role of the French judiciary continues to be impeded by the antimonarchical circumstances under which the Code Napoleon was drafted, the societal position of the German courts is largely a product of the historical exigencies that spurred judicial innovation. One interesting corollary of this more prestigious status is that German legal scholars do not generally question that judges can, and do, make law. Since capturing the moral high ground by declaring certain principles such as "good faith" supereminent, the courts have not ceded their power to serve as the conscience of the nation.<sup>57</sup> For example, the constitutionality of enacted law often hinges on the Constitutional Court's determination of whether the legislature has been faithful to principles of natural law, which are given only sketchy expression in the Civil Code and the Constitution.

These same historical differences are useful in explaining the style of German judicial writing, which is not unfamiliar to those schooled in the common-law tradition. Facts are developed, certainly more fully than in France and in Italy, and "full and careful formulations of doctrine"<sup>58</sup> are common. If anything, German legal decisions are more detailed than American or British opinions, reading "at times like small treatises,"<sup>59</sup> and relying more heavily on doctrinal writers than we are accustomed. The decisions thus furnish useful guidance to courts later called upon to resolve related issues. Indeed, German legal scholars praise "the open legal development" that such factual and legal detail allows;<sup>60</sup> a court action can then be properly compared to what has been done before and to overarching principles that the decisional law should support.<sup>61</sup>

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57. At least one scholar has argued that precedent has value in Germany not because subsequent courts treat it as binding law, but because, at least where "the decision expresses a general legal ethical principle corresponding to an established or developing general legal conviction," the people develop reliance on the court's interpretation. Karl Larenz, *The Open Legal Development: Germany*, reprinted in *THE ROLE OF JUDICIAL DECISIONS AND DOCTRINE* 133, 161 (Joseph Dainow ed., 1974). Professor Dawson believes that "judges can and do make law," and that "the issue . . . is no longer seriously debated." DAWSON, *supra* note 21, at 495.

58. DAWSON, *supra* note 21, at 494.

59. *Id.*

60. This phrase was borrowed from Larenz, *supra* note 57, at 133.

61. *Id.* at 134-40. Larenz identifies central principles that courts can and have relied upon in filling gaps in legislative schema: there arises an urgent need for a legal transaction, the "nature of the thing" considered demands judicial recognition not afforded by statute, or an overarching legal or ethical principle can only be served by recognizing a given right. The natural law check on positivism is evident in this approach, as it is in Larenz's further recognition that courts are sometimes compelled to actually rewrite legislation for the same reasons given above. His caveat that this latter power should be used

While principally intended to serve as a backdrop to analysis of early Continental product liability law, the foregoing discussion also makes a more general point about the danger of unchecked legislative supremacy. Where the courts are "told" simply to follow the statute, which is supposed to yield a predictable result, the danger is that the statute's inability to anticipate particular facts may encourage either unjust results, on the one hand, or strained—or disingenuous—readings so as to achieve justice, on the other. These possibilities multiply in those civil-code jurisdictions such as France and Italy that have a heritage of underdeveloped opinions, because a later court called upon to interpret the same provision lacks the benefit of a developed legal record. Paradoxically, in these jurisdictions judicial discretion is broadened rather than cabined.

In Germany, the United States, and Great Britain, more exhaustive opinions, to some extent a product of the openly acknowledged lawmaking role of the judicial branch, diminish but do not eliminate the peril of legislative tyranny.

### ***B. Pre-Directive Product Liability Law in the European Union: An Overview***

Before promulgation of the Directive, the development of product liability law in the member nations lagged noticeably behind that of the United States. Although the present section focuses on the substantive sources and effects of these differences, it should be noted that broader, systemic differences between domestic and European litigation have also figured significantly in the disparate development of product liability law.<sup>62</sup>

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sparingly, so as to husband political credibility for the undemocratic judiciary, has also been articulated by the United States Supreme Court. *See* *United States v. Carolene Prods.*, 304 U.S. 144, 152 (1938) (Court presumes constitutionality of regulatory legislation "unless in the light of the facts made known or generally assumed it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators.").

62. This split is between the United States and Europe, not between the United States and civil-law jurisdictions. In the United Kingdom, the losing party generally also pays the winner's court costs, but as Christopher Hodges, Solicitor of the Supreme Court of England and Wales, has pointed out, this decision is subject to the court's discretion, and generally results in a reduction of costs by some 30%. HODGES, *supra* note 16, at 675-76. A move to this position has recently been endorsed by the Republican controlled House of Representatives, as part of its "Contract with America." This provision, which is certain to face stiff opposition in the Senate—and a likely Presidential veto, if it gets that far—would affect all federal trials. *See* HOUSE COMM. ON COMMERCE, COMMON SENSE PRODUCT LIABILITY AND LEGAL REFORM ACT, H.R. REP. NO. 65, 104th Cong., 1st Sess., pt. 1 (1995).

Unlike his or her American counterpart, the unsuccessful European litigant generally pays the other side's court costs and attorneys' fees,<sup>63</sup> thereby discouraging cases in which liability is less than assured. Further, contingency fee arrangements are typically not permitted,<sup>64</sup> thereby effectively barring less well-heeled injured parties from judicial redress in all but the clearest cases.

Additionally, most nations show far less willingness, if they are willing at all, to allow recovery for pain and suffering.<sup>65</sup> The potential for relatively large pain and suffering awards is thought by many to encourage litigation, a conclusion that seems sensible. In addition, the ready availability of state-funded health services reduces the incentive to litigate,<sup>66</sup> especially where the recovery cannot be augmented by pain and suffering damages.<sup>67</sup>

These initial disadvantages are multiplied through differences in product liability law itself. Most centrally, the strict liability for defective injury-causing products that has been recognized, in one form or another, in the United States for several decades was largely unknown in the European Union before the promulgation of the Directive.<sup>68</sup> As we have seen, civil-law jurisdictions at least nominally required that liability be pegged to a specific code section. Not surprisingly, tort and contract provisions were the most commonly invoked vehicles for recovery. Inasmuch as the codes required negligence in order

63. See Orban, *supra* note 16, at 393.

64. The absence of the contingency fee arrangement coupled with the potential payment of legal fees to the opposition imposes a large financial risk on the European plaintiff. *Id.*

65. Nilles, *supra* note 16, at 737 n.38.

66. See Orban, *supra* note 16, at 393. The author also suggests that in European countries lesser discrepancies generally exist between what can be recovered through courts and what can be recovered under workers compensation, thereby further reducing the incentive to litigate.

67. Inasmuch as these differences are not specific to product liability litigation, they lie beyond the consideration of this Article. Yet these differences must be recognized and considered before any kind of real uniformity of result can be achieved. For the reasons developed in Part IV, such uniformity is a *desideratum*.

68. One enormous exception to this general principle is the German Pharmaceutical Law of 1976 which imposed strict liability for injury-causing pharmaceuticals. *Arzneimittelgesetz* [Pharmaceutical Act], Aug. 24, 1976, *Bundesgesetzblatt*, Teil I [BGBl.I] 2445. Article 84 is the source of such liability, but the liability is limited in two significant respects: First, the drug's harmful effects must exceed acceptable bounds, as determined by relevant medical opinion. This requirement is intended to block suits alleging what amount to relatively minor side effects. The second qualification is familiar enough to American product liability lawyers: the adequacy or presence *vel non* of warnings is judged against a negligence standard. See Nilles, *supra* note 16, at 740 n.57.

to find tort liability,<sup>69</sup> recovery was much less certain than in the United States.<sup>70</sup> Contractual recovery was impeded by the same pesky privity requirement that had dogged American product liability law until the landmark decision in *Henningsen v. Bloomfield Motors, Inc.*<sup>71</sup> To place the Directive in context by pointing out the inadequacies of the prior doctrine, I now proceed to a more detailed examination of these liability. Given this limited purpose, I have again chosen France, Italy, and Germany as representatives of the kinds of treatment received product liability in the pre-Directive era. Other jurisdictions will be mentioned only as they reinforce or contradict these examples.

### 1. France

France provides a most striking illustration of judicial creativity in the face of legislative inaction and the stated principle of legislative supremacy. At least one commentator has suggested that in France the Directive may not provide the plaintiff with any recovery that was not already available.<sup>72</sup> This striking conclusion deserves investigation.

Product liability law in France is governed by both tort and contract principles. Articles 1382-86 of the Civil Code, particularly Articles 1382<sup>73</sup> and 1383,<sup>74</sup> provide the source of tort liability. Inasmuch as these sections, by their terms, require negligence as a condition of liability, it seems that the Directive's strict liability would be wel-

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69. Similarly, in England, recovery depended critically upon a showing of negligence. For a thorough discussion of the state of product liability law in that country before the Directive, see WARREN FRIEDMAN, 1 INTERNATIONAL PRODUCTS LIABILITY 234-39 (1986). The issue whether to impose strict liability was the subject of investigation and serious debate at the time that the Directive was first proposed. In light of that proposal, however, the Royal Commission on Civil Liability and Compensation for Personal Injury in 1978 qualified its recommendation of strict liability with the wish that further consideration of legal reform in the product area be deferred pending consideration of the proposed Directive. Nilles, *supra* note 16, at 738-39.

70. Courts in France, Germany, Belgium, Ireland, and the United Kingdom have eased plaintiffs' paths by allowing a presumption of negligence. However, the courts of these countries "generally allow the producer to rebut this presumption by showing the exercise of care." Nilles, *supra* note 16, at 735 n.27.

71. 161 A.2d 69 (N.J. 1960).

72. The same is true in Belgium, where the jurisprudence also derives from the Code Napoleon. See HODGES, *supra* note 16, at 238-40 (Belgium), 316-26 (France).

73. "Any act whatever of man which causes damage to another obliges him by whose fault it occurred to make reparation." CODE CIVIL [C. Civ.] art. 1382 (Fr.).

74. "Each one is liable for the damage which he causes not only by his own act but also by his negligence or imprudence." C. Civ. art. 1383 (Fr.).

came by injured consumers. In a flash of judicial policy-making, however, the French Cour de Cassation, supported by the lower courts, established an irrebuttable presumption of manufacturer negligence; this approach effectively makes liability strict.<sup>75</sup> So much for legislative supremacy. It is also worth noting that, in calling the presumption irrebuttable, the French judiciary has exceeded even the early American approach of using *res ipsa loquitur* to establish an inference of negligence.<sup>76</sup>

Proper plaintiffs under the tort sections, however, do *not* include the buyer. Thus, the sections apply only to nonpurchasing third parties, ranging from members of the buyer's family to remote bystanders. The buyer must sue under the contractual sections of the Code. Liability for breach is therefore strict, so that it might appear that purchasing plaintiffs stand in virtually the same position as injured third parties.

American product liability lawyers and scholars are well aware of the theoretical "fit problem" with warranty law, as applied to personal injuries caused by defective products. These limitations have been duly recognized at least since Justice Traynor's opinion in *Escola v. Coca-Cola Bottling Co.*<sup>77</sup> First, there is a threshold problem that warranty recovery might have been limited to recovery of the purchase price or the replacement of defective goods. Similarly, even though the Uniform Commercial Code (UCC)—for reasons having much to do with the state of product liability doctrine at the time of the Code's drafting—specifically extends to recovery for personal injuries, the implied warranties of merchantability and of fitness for a particular purpose can in theory be disclaimed.<sup>78</sup> Further, the requirement of prompt notice and the running of the statute from the date of sale can

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75. See Shettler, *supra* note 16, at 171. See also Hans Taschner, *La Future Responsabilité du Fait des Produits Défectueux dans la Communauté Européenne*, 297 *REVUE DE MARCHÉ COMMUN* 257, 258 (1986) (in France and Luxembourg, and to a certain extent, in Belgium, "la jurisprudence . . . a progressivement instaurée [la responsabilité objective de facto] par le biais d'une présomption de faute irréfragable.")

76. The best-known example of the (mis)use of *res ipsa loquitur* in a defective product case is probably *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944).

77. 150 P.2d at 440 (Traynor, J., concurring).

78. Again, this problem was anticipated by the drafters of the Uniform Commercial Code, who provided that any limitation of liability for personal injuries is "*prima facie* unconscionable." U.C.C. § 2-719(3) (1994). Since strict liability in tort was not then a *fait accompli*, the drafters of the U.C.C. extended protection this far. The discerning reader will note that § 2-719 does not by its terms prohibit the seller from totally disclaiming all warranties, express or implied; courts have on occasion permitted such disclaimers. See *Ford Motor Co. v. Moulton*, 511 S.W.2d 690, 693 (Tenn. 1974).

trap the unwary consumer.<sup>79</sup> Perhaps most importantly, locating recovery within the contract may have meant that the buyer had only a remedy against the immediate seller, although the party who should be sued is the manufacturer.<sup>80</sup>

Courts in the United States had, by degrees, eliminated most of these problems by the time the principle of strict liability in tort was finally judicially proclaimed in *Greenman v. Yuba Power Products, Inc.*<sup>81</sup> In fact, judicial willingness to overlook the formal structure of warranty law in order to afford recovery to injured buyers<sup>82</sup> spurred Traynor's call for strict liability in tort; why bend contract law when, in his view, sound reasons of policy supported tort liability?

The French courts have overcome most of these same hurdles, sometimes with the assistance of the Code itself. Perhaps because of continued deference to the *structure* of liability imposed by the Code, however, the extra step of shifting to tort liability has not been taken.

As suggested above, the Code Napoleon is more generous to injured plaintiffs than the Uniform Commercial Code. For example, under the Code Napoleon, the statute of limitations begins to run from the time of sale, but the limitations period is thirty years.<sup>83</sup> In contrast, the comparable period under the Uniform Commercial Code is four years. In addition, the courts have simply rewritten Article 1643, which parallels the Uniform Commercial Code in facially per-

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79. These requirements have been somewhat eroded by case law in some jurisdictions. For example, the New York Court of Appeals allowed the U.C.C.'s statute of limitations to be overridden by the state's tort rule, measuring accrual from the date of injury. *Victorson v. Bock Laundry Machine Co.*, 335 N.E.2d 275 (N.Y. 1975). As to notice, courts have either relaxed the requirement, as in *Wojciuk v. Rubber Co.*, 122 N.W.2d 737 (Wis. 1963) (informally notifying the seller that the tires had blown out was sufficient), or have held it inapplicable to a nonpurchaser. *Frericks v. General Motors Corp.*, 363 A.2d 460 (Md. 1976).

80. The hedged language in the text is attributable to an ambiguity in U.C.C. § 2-318 (1992), which, depending upon which of three alternatives a particular state adopts, attenuates or abolishes problems with horizontal privity in which the injured party is other than the consumer/purchaser. Whether that section was also intended to affect "downstream," or vertical, privity is much less clear. Alternative C, the most liberal from an injured party's point of view, extends a seller's liability for breach of warranty "to any person who may reasonably be expected to use, consume, or be affected by the goods and who is injured by breach of the warranty." Is this text intended simply to extend liability further across the range of nonpurchasers or to do away with vertical privity as well? The issue soon became academic as the New Jersey Supreme Court, in *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960), began an avalanche of decisions judicially abolishing vertical privity.

81. 377 P.2d 897 (Cal. 1962).

82. See, e.g., *Greenberg v. Lorenz*, 173 N.E.2d 773 (N.Y. 1961).

83. See *Shettler*, *supra* note 16, at 170 n.136.

mitting good faith exclusions of liability.<sup>84</sup> Moving in step with American courts, the French judiciary has not permitted such exclusions in practice.<sup>85</sup> Finally, plaintiffs have been permitted to proceed directly against the manufacturer in spite of the lack of privity typical in a mass-marketing situation.<sup>86</sup> Nonetheless, the warranty solution is not wholly salutary; the notice problem, for example, has remained.<sup>87</sup>

The Byzantine structure of French product liability law in the pre-Directive era teaches more than one lesson. Most obviously, it is beneficial to replace the unwieldy, bifurcated system created by the Code and the judiciary with the streamlined approach taken by the Directive.<sup>88</sup> Furthermore, the Directive's mandate to create implementing legislation perforce ends legislative inaction—inaction that had spurred the judicial branch to submerge the tenet of legislative supremacy in favor of achieving results it thought just.

## 2. Italy

Matters are considerably simpler for those injured by defective products in Italy. Although both contract and tort provisions of the Italian Civil Code can theoretically be used, in practice the restrictions imposed under the Code's contract law—which the judiciary has *not* been willing to ignore—make such a course fruitless. First, privity holds fast: contractual liability is limited to the direct seller, and nonpurchasers have no remedy even against that party.<sup>89</sup> Second, a difficulty with warranty law that American and French courts have long since surmounted remains in Italy: remedy is limited to a reduction in purchase price or a rescission of the contract.<sup>90</sup> Third, warranties may be limited or excluded entirely.<sup>91</sup> Fourth, the time limits imposed by both the notice requirement and the statute of limitations

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84. Article 1643 states, in pertinent part: "[The seller] is liable for hidden defects, even though he did not know of them, unless, in such case, he had stipulated that he would not be obligated for any guaranty." C. Civ. art. 1643 (Fr.).

85. See HODGES, *supra* note 16, at 320-21.

86. See Orban, *supra* note 16, at 348, making the point that the French courts eased plaintiffs' paths toward recovery by not requiring successive actions along the chain of manufacture, distribution, and sale.

87. Article 1648 of the Code states: "An action resulting from defects of an annulling character must be brought by the buyer within a brief delay according to the nature of the defects . . . and the usage of the place where the sale was made." C. Civ. art. 1648 (Fr.).

88. Yet streamlining will not eliminate the need for judicial creativity in fashioning solutions along the complex spectrum of defective product cases.

89. See Shettler, *supra* note 16, at 167 n.104.

90. *Id.* at n.100.

91. *Id.* at n.101.



will frustrate many claims. Absent contrary agreement, the purchaser must inform the seller of a defect within eight days of its discovery, and must bring all actions within one year of the delivery date.<sup>92</sup> Finally, and most surprisingly, the purchaser must prove that the seller was at least negligent in not knowing of the defect at the time of the contract.<sup>93</sup>

While this contractual remedy may be useful to the disappointed commercial buyer, it does not provide the kind of relief demanded by those personal injury plaintiffs fortunate enough to come within its coverage. The tort provisions of the Italian Civil Code, however, are somewhat more generous: the basic tort provision enshrined in Article 2043 imposes a general duty of care on everyone, which of course includes creators of injury-causing products.<sup>94</sup> As is true in all jurisdictions, plaintiffs must show that the product was defective and that it caused injury.<sup>95</sup>

The Italian courts had generally been unwilling, however, to permit plaintiffs to sidestep the high hurdle of demonstrating negligence.<sup>96</sup> Although some courts had moved toward a "presumed negligence" rule, the cases were in conflict, and no steady movement in that direction was apparent. Another possible avenue of recovery used in some cases was something close to the American position of strict liability for dangerous activities. Nonetheless, the majority of courts had not been willing to go so far.<sup>97</sup>

Despite their courts' professed deference to the legislative will, a jurisprudence of product liability has emerged in France and Italy that is only consistent with the relevant code to the extent that such consistency suits judicial temper. This conclusion is especially easy to draw in France, where courts have remade warranty law in the image of strict tort liability. Similarly, at least some Italian courts have managed to avoid the strictures of negligence, thereby compensating injured consumers in defiance of codal prohibition.

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92. *Id.* at n.102.

93. *Id.* at n.99.

94. *Id.* at 167-68 n.106.

95. *Id.* at 168 n.107.

96. Nilles, *supra* note 16, at 735.

97. The Italian Civil Code provides at Article 2050: "[W]hoever causes injury to another in performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable to pay compensation unless he proves that he has taken all suitable measures to avoid the injury." CODICE CIVILE [C.C.] art. 2050 (Italy). Even if applied, the section does not literally create strict liability, since the defendant has available the defense that he or she had taken "all suitable measures" to prevent the injury.

### 3. *The Federal Republic of Germany*

In Germany<sup>98</sup> as in Italy, restrictions against recovery under warranty theory have driven those injured by products to the friendlier shores hospitable region of tort law. While it is true that a proper plaintiff may sue under both theories at once, since warranty liability is strict,<sup>99</sup> the advantages of suing under contract principles end there. The seller can exclude liability;<sup>100</sup> there is a six-month statute of limitations period;<sup>101</sup> only those in privity of contract can sue;<sup>102</sup> and remedies open to those plaintiffs able to negotiate the preceding obstacles are limited to return, repair, or price reduction.<sup>103</sup>

Tort liability in the pre-Directive German Republic fell somewhere between that of France and Italy. Liability issues arose from section 823(1), which requires compensation from anyone "who, wilfully or negligently, unlawfully injures the life, body, health, freedom, property or other right of another."<sup>104</sup> Faced with a code provision drafted long before the emergence of product liability, the German judiciary has compromised; negligence is required, but injured plaintiffs benefit from a presumption of negligence which the manufacturer must rebut.<sup>105</sup> Plaintiffs are also assisted by an extremely generous statute of limitations—in most cases, thirty years.<sup>106</sup>

Again, the German judicial system, faced with code sections never intended to solve problems relating to mass-marketed defective

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98. I here discuss what was popularly called "West Germany," which was the repository of the German Civil Code under discussion in the period immediately preceding the Directive.

99. Section 459 so provides: "The seller of a thing warrants the purchaser that, at the time when the risk passes to the purchaser, it is free from defects which diminish or destroy its value or fitness for its ordinary use, or the use provided for in the contract . . . . The seller also warrants that, at the time the risk passes, the thing has the promised qualities." BÜRGERLICHES GESETZBUCH [BGB] art. 459 (F.R.G.).

100. Shettler, *supra* note 16, at 169 n.121 (citing Orban, *supra* note 16, at 352).

101. *Id.*

102. *Id.*

103. *Id.* at 169 n.120 (citing B. VON BRAUNSCHWEIG, A MANUAL OF PRACTICE IN SELECTED NATIONS, FEDERAL REPUBLIC OF GERMANY 7 (1981)). Consequential and unforeseeable damages may be available if fraud or misrepresentation by the seller can be proven. *Id.*

104. BGB art. 823 (F.R.G.).

105. Needless to say, this presumption of negligence is of no help to plaintiffs who wish, or need, to sue some other party in the chain of distribution. It applies only against the party who caused the defect. Shettler, *supra* note 16, at 169-70 (citing VON BRAUNSCHWEIG, *supra* note 103, at 28).

106. The statute of limitations is three years where the plaintiff has knowledge of the injury and the person who caused it. Shettler, *supra* note 16, at 170 (citing KLUWER-HAR-RAP, PRODUCT LIABILITY IN EUROPE 83 (1975)).

products, has come up with a solution that gives little more than a nod to the code. As we have seen, however, in Germany this creativity is as likely to be admired as condemned, since the doctrine of legislative supremacy is not rigorously followed, and scholarly and political assessment of the courts' innovations centers on the merits of what the court has done, rather than bogging down in complaints about unwarranted arrogations of power.

### **III. Reforming Product Liability Law—The European Community's Product Liability Directives**

The present section undertakes an analysis of the Directive. Such an analysis is important, not only to enable an understanding of the Directive's provisions,<sup>107</sup> but also to understand the practical impact that this ambitious attempt at reform is likely to have.

Preliminarily, some of the problems likely to plague the Directive's effectiveness are external to its text. First, although courts have sometimes balked at their assigned second-class role, local interpretations of the proper relationship between the court and the legislature may nonetheless make courts of a particular country unwilling to interpret the Directive with the flexibility that its language requires. If it is seen as "code-like," courts may overemphasize strict interpretation of the text, thereby frustrating justice in particular cases. If those same courts then combine this approach with continued unwillingness to consider decided cases—both pre- and post-Directive—in resolving new matters, progress toward a coherent law of product liability may be fitful or entirely frustrated.

Second, and at least as important as de jure judicial modesty, the European civil plaintiff generally labors under disadvantages that may prevent full benefit of protection for the product-injured consumer. These disadvantages, discussed in Part II, *supra*, need not be reiterated here. But, consider whether a lower-middle class or poor product liability plaintiff would proceed with a unique or risky claim—even an objectively meritorious one—without a contingency fee ar-

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107. Able commentaries on the Directive have thus far been provided by Heinz J. Dielmann, *The EEC's Council Directive on Product Liability*, 20 INT'L LAW. 1391, 1391-99 (1986); Marshall S. Shapo, *Comparing Products Liability: Concepts in European and American Law*, 26 CORNELL INT'L L.J. 279, 323 (1993); Simon Whittaker, *The EEC Directive on Product Liability*, 5 Y.B. EUR. L. 233 (1986).

rangement and faced with the prospect of being assessed court costs in the event of a loss.<sup>108</sup>

The subject of the present section, however, is not the daunting national obstacles awaiting the Directive. Rather, the thrust will be on the internal limitations of that text itself, limitations stemming from two discrete sources. First, I enclose the Directive within the context of its drafting. That context is one of compromise and contention, and the resulting document bears the scars of its promulgation. Forced to allow "home rule" options on some of the most crucial provisions, the Directive betrays its own promise of providing uniformly fair treatment to all product liability litigants.

The second part of this section discusses the substantive commands that did find their way into the Directive. Although these also contain problems, they are nonetheless promising; in fact, I prefer the Directive's approach to the grand issue of "defect" to the more elaborately developed solution under the Model Uniform Product Liability Act. But, beyond introducing strict liability—which, as always, is not truly strict—the Directive is confronted by the same intractable inability to predict future problems that afflicts every attempt at codifying product defect law. Indeed, for reasons made clear in Part IV, *infra*, the better approach is to focus on procedural reform. The Directive does little of that, and what it does accomplish is not uniformly for the better.

### A. *Genesis of the Product Liability Directive*

The European Economic Community was established in 1957 by the signing of the Treaty of Rome.<sup>109</sup> The European Community

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108. See Larry T. Yanawitch, Note, *The European Community's Products Liability Directive: Is the U.S. Experience Applicable?*, 18 L. & POL'Y INT'L BUS. 795, 810-11 (1986). A related issue is the lower threshold of 500 ECU for claims for damage to property in Article 9, thus prohibiting a remedy under the Directive for the plaintiff with a "small" claim. "The relatively richer consumer would thus have an extra remedy for damage to his valuable property, whereas the poorer consumer would not have a remedy for his less valuable property." Whittaker, *supra* note 107, at 275.

109. Treaty Establishing the European Economic Community, Mar. 25, 1957, 293 U.N.T.S. 11 [hereinafter the Treaty of Rome]. Article 240 established the Community "for an unlimited period of time." Books and articles tracing the development of the Community since that time are legion. See, e.g., T. C. HARTLEY, *THE FOUNDATIONS OF EUROPEAN COMMUNITY LAW* (2nd ed. 1988); PAOLO MENGIOZZI, *EUROPEAN COMMUNITY LAW FROM COMMON MARKET TO EUROPEAN UNION* (1992); Nicola Preston, *Several States, One Unity, One Law?*, 24 AKRON L. REV. 141 (1990).

(EC), as it subsequently became known,<sup>110</sup> currently has fifteen members,<sup>111</sup> and others are clamoring to join.<sup>112</sup>

The Community legislates both directly through regulation and indirectly through directives.<sup>113</sup> The process by which a directive is promulgated has been detailed elsewhere.<sup>114</sup> Nonetheless, a brief explanation is in order.

### 1. *The Process of Directive Drafting, Consulting, and Adoption*

The Commission of the EC, comprising of seventeen Commissioners representing all of the member states, initiates the process by drafting proposals for directives. The Commissioners are expected to represent the interests of the entire Community, not simply those of their home nations.<sup>115</sup> The Council of Ministers, consisting of one representative from each state, has the power to adopt these initiatives into law. The Council's membership changes depending on the subject of the directive under consideration. Thus, national ministers of varying portfolios are sent to Brussels to confer and to vote on matters within their particular expertise.<sup>116</sup> Although proposals are

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110. This name change reflected that the "community" had become one of a host of shared interests, of which economics is only one, albeit still the most important. As stated earlier, the name has more recently been changed again, this time to the European Union. See *supra*, note 17. I have for the most part used the European Union terminology herein, except where that term would be historically inaccurate. The entity that promulgated the Directive, for example, was the European Community.

111. Until recently, the membership included: Belgium, Denmark, Germany, Greece, France, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and the United Kingdom. Treaty of Rome, *supra* note 109, art. 148. These twelve have recently been joined by Austria (voted to join in June 1994; entry becomes effective Jan. 1, 1995), Finland (voted to join in Oct. 1994; entry became effective on Jan. 1, 1995), and Sweden (voted to join in Nov. 1994; entry became effective on Jan. 1, 1995). Bucking the trend, Norwegian voters rejected membership on November 29, 1994. John Darnton, *Vote in Norway Blocks Joining Europe's Union*, N.Y. TIMES, Nov. 29, 1994, at A1.

112. "Recent applications for European Community membership [include] Turkey in 1988, Austria in 1989, Malta and Cyprus in 1990, Sweden in 1991, Finland in 1992 and . . . the new democracies of Eastern Europe would also like to join." See Joseph L. Brand, *The New World Order Of Regional Trading Blocs*, 8 AM. U. J. INT'L L. & POL'Y 155, 163 n.28. (1992) (citing JONATHAN DAVIDSON, *THE EUROPEAN COMMUNITY IN THE NINETIES* 4 (1992)). Now, Poland, Hungary, and the Czech Republic are also seeking membership. Howard LaFranchi & Francine S. Kiefer, *EC Girds Itself for Inevitable Expansion*, CHRISTIAN SCI. MONITOR, Dec. 24, 1991, at 5.

113. Treaty of Rome, *supra* note 109, art. 235.

114. See, e.g., Anthony Arnall, Note, *The Direct Effect of Directives: Grasping the Nettle*, 35 INT'L & COMP. L.Q. 939 (1986); MINGOZZI, *supra* note 109, at 90-98.

115. See GEORGE A. BERMAN ET AL., *CASES AND MATERIALS ON EUROPEAN COMMUNITY LAW* 57-59 (1993).

116. *Id.* at 51-53.

sent directly from the Commission to the Council, Council members do not act until the proposal at issue is sent to the European Parliament for consultation.<sup>117</sup> Article 138 of the Treaty of Rome provides that members of the European Parliament are to be elected "by direct universal suffrage" within the individual member states and specifies the number to be selected from each state.<sup>118</sup> These members typically are not representatives of their own nation's government. More importantly, these members of Parliament do not vote on the directives because their function is one of consultation.<sup>119</sup> The apparent paradox is that while the Parliament is the most democratic of EC institutions, it has little actual power.<sup>120</sup> After consultation with Parliament, and often with the Economic and Social Committee as well,<sup>121</sup> the proposal may return to the Commission for redrafting. Before acting on the updated directive, the Council may choose to resubmit it to the Parliament for further consultation. The Council then adopts the final version of the directive, which member states are required to adopt within a certain period of time.<sup>122</sup>

A directive establishes community policy, leaving the specifics of implementation to the member states.<sup>123</sup> This two-step process sows seeds of disharmony which germinate when each individual state funnels the directive through its unique legislative apparatus. This problem is compounded when, as is true of certain provisions of the Product Liability Directive, states are afforded two or more options with respect to certain provisions.

## 2. *The Product Liability Directive's Tortured Path to Adoption*

Although the actual process of member state approval of directives means that "harmonization" is a bit of a misnomer, its achievement remains a signal goal of the Community, as evidenced by the

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117. *Id.* at 66.

118. *Id.* at 64.

119. By the terms of the 1992 Treaty on European Union, Parliament received outright decision-making power in some cases. *Id.* at 66.

120. *See id.* at 93-94.

121. The Economic and Social Committee is composed of members appointed by individual governments to represent three overarching groups: employers, employees, and various other coalitions, such as farmers and consumers. *Id.* at 83 n.4.

122. This complicated procedure is explained well in Bermann. *See id.* at 79-90.

123. "Directives shall bind any Member State to which they are addressed, as to the result to be achieved, while leaving to domestic agencies a competence as to forms and means." Treaty of Rome, *supra* note 109, art. 189, para. 3.

language of the Treaty of Rome itself.<sup>124</sup> As far back as 1974, when the product liability directive was first proposed, three separate rationales were offered in its support: harmonization would equalize competition among member states, promote the free movement of goods, and foster equal protection of the consumer.<sup>125</sup>

The Directive that finally emerged in July 1985 expressly adopts these purposes in "the Preamble": "Approximation of the laws of the Member States concerning the liability of the producer . . . is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer . . . ."<sup>126</sup> For the reasons developed below, the path to the foregoing statement was rocky.

Under one view of European integration, since the Treaty of Rome provides no express authority for "improving" national laws deemed inadequate, directives should be written only to further the goal of harmony and are within the EC's legal competence only to the extent that they do so. The European Parliament initially questioned the legal basis for the product liability directive on the related grounds that the Directive did not "*directly affect* the establishment or *functioning of the common market*,"<sup>127</sup> and that increasing consumer protection was not a proper subject for Community governance.<sup>128</sup>

Strictly speaking, since harmonization can be achieved without affording any increased protection to the consumer, the Parliament's argument has a certain logic. As evidenced by the Preamble cited earlier, a broader view of the Council's power ultimately prevailed. That view assumes that European integration should always seek the "optimal legal solution in light of the present requirements of the [Communi-

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124. Article 100 of that document empowers the EC Council of Ministers to "issue directives for the approximation of such provisions of the Member States as have a direct incidence on the establishment or functioning of the Common Market." *Id.* art. 100.

125. COMMISSION OF THE EUROPEAN COMMUNITIES, MEMORANDUM ON THE APPROXIMATION OF THE LAWS OF MEMBER STATES RELATING TO PRODUCT LIABILITY 4 (Working Group "Product Liability" Working Document No. 1, Aug. 1974) [hereinafter 1974 Working Document] *cited in* Nilles, *supra* note 16, at 742-44 n.78.

126. Directive, *supra* note 3, pmbl.

127. Report of the Legal Affairs Committee, EUR. PARL. DOC. (COM 246) 7 (1978-79) (citing Article 100) (emphasis in original).

128. Some have thought that such an approach would require the Council to search for, and to then enshrine into directives, the lowest common denominator among constituent nation legislation. Nilles, *supra* note 16, at 744 n.86 (citing Hans von der Groeben, Speech to the European Parliament (Nov. 19, 1969), *in* EUR. PARL. DEB. (119) 148 (Nov. 27, 1969)). This position overstates the problem. At most, the narrow view of EC power, pressed logically, would seem to restrict the permissible subject of directives to those already found in member states' laws.

nity]."<sup>129</sup> With a recent spate of highly specific, regulatory-type directives promoting consumer safety and welfare, this latter interpretation has been ascendant of late.<sup>130</sup>

As became clear in subsequent wrangling between the Commission and the Parliament, the latter's central concern was not with the issue of the Directive's legal foundation, but with its imposition of liability even for risks that the producer could not have known about—so-called "development risks."<sup>131</sup> After the Council, the Commission, and the Parliament had gone a few rounds on the development risk issue, an industry-friendly compromise was reached. Article 7(e) of the Directive allows the producer to escape liability upon a showing that, given existing scientific and technological knowledge at the time of the product's circulation, the defect could not have been discovered.

Article 15 appeased advocates of true strict liability by allowing, in subsection (1)(b), derogations by member states from the provisions of Article 7(e). States wishing to avail themselves of this derogation, however, must "communicate the text of the proposed measure to the Commission [which] shall inform the other Member States thereof."<sup>132</sup> The Commission then must decide whether to propose amending the directive to create liability for development risks, and

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129. Nilles, *supra* note 16, at 744 n.86. Nilles also makes the point that the Legal Affairs Committee of the European Parliament agreed to drop its *ultra vires* objections only when they believed they had struck an agreement with the Commission to exonerate producers from development risks. When the Commission subsequently refused to exclude such risks from liability, Committee members were incensed. *Id.* at 753 n.143.

130. Council Directive 87/357 regarding products which, despite their appearance, endanger the health or safety of consumers, 1987 O.J. (L 192) 49; Council Directive 88/378 on approximation of the laws of the member states concerning the safety of toys, 1988 O.J. (L 187) 1; Council Directive 92/59 on general product safety, 1992 O.J. (L 228) 24; Council Resolution on a second program of the EEC for a consumer protection and information policy, 1981 O.J. (C 133) 1; Council Regulation 2455/92 on export and import of certain dangerous chemicals, 1992 O.J. (L 251) 13; Council Directive 89/391 regarding measures to encourage improvements in the safety and health of workers at work, 1989 O.J. (L 183) 1; Council Directive 93/13 on unfair terms in consumer contracts, 1993 O.J. (L 95) 29; Council Directive 93/43 on hygiene of foodstuffs, 1993 O.J. (L 175) 1; Council Directive 92/57 on implementation of minimum safety and health requirements at temporary or mobile construction sites, 1992 O.J. (L 245) 6.

131. This same issue has been labelled the state of the art defense in the United States. Fuller comparisons of the two terms appear *infra* in subparts III.B.4, IV.B.1(c). Expressing a concern familiar to readers of American opinions concerned with liability for defects not known at the time of product manufacture, the European Parliament was worried that liability for development risks would restrict innovation, increase producer costs, and generally weaken industry. Nilles, *supra* note 16, at 750.

132. Directive, *supra* note 3, art. 15, para. 2.



the member state proposing the derogation must hold its law in abeyance until that decision is reached. If the Commission does decide to press for amendment, a further waiting period is mandated.<sup>133</sup>

One other area of debate during the lengthy drafting process should be mentioned. The Commission, which favored true strict liability from the outset, believed that a total damage cap for defects of a particular type was necessary to keep manufacturers' liability from spiralling out of control. The Commission declined, however, to establish individual damage caps, at least for personal injury.<sup>134</sup>

The Economic and Social Committee strongly disagreed on both counts, favoring a cap on individual damages, but expressing dismay over the prospect of uncompensated injury for mass disasters if an overall cap were established.

Here, the Commission largely prevailed. Article 9(a) sets no limit on recovery for personal injuries or death. As to an overall limit, a compromise was again struck: Article 16(1) allows a member state to limit overall damages "caused by identical items with the same defect" provided that the limitation not fall below 70 million ECU. Perhaps to assuage the concerns expressed by the Economic and Social Committee, Article 16 (2) then provides that:

Ten years after the date of notification of this directive, the Commission shall submit to the Council a report on the effect on consumer protection and the functioning of the common market of the implementation of the financial limit . . . . [T]he Council, acting on a proposal from the Commission . . . shall [then] decide whether to repeal paragraph 1.<sup>135</sup>

### 3. *Status of Member State Implementation of the Directive*

After resolving these internecine disagreements, the EC's constituent decision-makers adopted the Product Liability Directive on July

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133. *Id.*

134. The Directive does contain a damage limitation where the damage is to property. Article 9(b) states that property damage begins at the "lower threshold of 500 ECU," and that even those damages are only recoverable where the property damaged was ordinarily used, and was also used by the injured party, primarily for personal use and consumption. *Id.* art. 9 (b) (i)-(ii). This important limitation is presumably to excise the realm of commercial dealing from the Directive's reach. This issue has greatly vexed American courts, with the great majority holding that commercial losses—most typically those resulting from damage to the product itself—should be dealt with under the Uniform Commercial Code, not under tort law. *East River Steamship Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858 (1986).

135. Directive, *supra* note 3, art. 16(2).

25, 1985. Article 19 of the Directive provided that member states were to "bring into force, not later than [July 30, 1988], the laws, regulations and administrative provisions necessary to comply."<sup>136</sup>

As of the present writing, most members of the EC, as well as new members Austria, Sweden, and Finland, had adopted the Directive.<sup>137</sup> In addition, Norway, which recently rejected membership into the EC, has adopted the principles of the EC Product Liability Directive into its national laws.<sup>138</sup> The decisions made by the EC nations on the options left open by Articles 7(e) and 16, as well as an additional option regarding liability for certain non-manufactured products, are discussed *infra* in subpart III.B.4.

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136. *Id.* art. 19. The Directive was sent to member states on July 30, 1985, and the text omitted from the quoted material provides three years from the date of notification.

137. Legislation by which EEC member countries enacted the Directive includes: Austria: Produkthaftungsgesetz [Federal Product Liability Act of January 21, 1985] (Effective July 1, 1988 and enacted before Austria joined the EEC, but deliberately based on the Directive); Belgium: Loi Relative à la Responsabilité du Fait des Produits Défectueux [Act of Feb. 25, 1991 on Defective Product Liability] (Effective Apr. 1, 1991); Denmark: Lov. nr. 371 af 7. Juni 1989 om Produktansvar [Products Liability Act No. 371 of June 7, 1989] (Effective June 10, 1989); Finland: Tuotevastuulaki No. 694 [Product Liability Act No. 694] (Effective Sept. 1, 1991, with amendments passed in Jan. 1993); France: De la Responsabilité du Fait du Défaut de Sécurité des Produits [Product Liability Resulting from Lack of Safety (draft act as of June 11, 1992)] (The purpose of this act is to harmonize French Product Liability law with the Directive); Germany: Produkthaftungsgesetz [Product Liability Act] (Effective Jan. 1, 1990, and applicable to products put into circulation on or after Oct. 3, 1990); Greece: Act 1961/1991 Consumer Protection and other Provisions, ch. 3, "Liability of the Producer for Defective Products," §§ 7-17 (Effective July 30, 1993); Ireland: The Liability for Defective Products Act 1991 (Effective Dec. 16, 1991); Italy: Infortuni sul Lavoro e Igiene (Prevenzione Degli) Presidential Decree No. 224 of May 24, 1988 (Effective May 24, 1988); Luxembourg: Loi du 21 Avril 1989 Relative à la Responsabilité Civile du Fait des Produits Défectueux [Act of Apr. 21, 1989, on Civil Liability for Defective Products] (Effective May 2, 1991); The Netherlands: Wet van 13 September 1990, Houdende Aanpassing van het Burgerlijk Wetboek aan de Richtlijn van de Raad van de Europese Gemeenschappen Inzake de Aansprakelijkheid voor Producten met Gebreken [Act of Sept. 13, 1990, to Adapt the Civil Code to the Directive of the Council of the European Communities on Liability for Defective Products] (Effective Nov. 1, 1990); Portugal: Decreto-lei No. 383/89 de 6 de Novembro [Decree-law number 383/89 of Nov. 6, 1989] (Effective Nov. 11, 1989); Spain: Draft Act on Civil Liability for Damages Caused by Defective Products; Sweden: Produktansvarlag 1992:18 [The Product Liability Act] (Effective Jan. 1, 1993, and only applies to products put into circulation after that date); United Kingdom: Consumer Protection Act 1987 (Effective Mar. 1, 1988).

138. Lov om Produktansvar av 23.12 1988 Nr. 104, Endret Ved Lov av 27.11.1992 Nr. 112 [The Product Liability Act of December 23, 1988, No. 104, amended by Act of November 27, 1992, No. 112] (Effective Jan. 1, 1989; amendments effective on date EEC Treaty enters into force).

## B. Analysis of the Product Liability Directive

The Directive is remarkable for its terseness of presentation. In contrast to reform statutes in the United States, the Directive's economical text runs only five pages. In addition, for good or ill, the drafters did not copy the domestic predilection for appending analytical notes. The only explanation of the intent underlying the Directive's skeletal commands is contained in the Preamble, which combines reiteration, slight expansion, and apparent contradiction.

What the Directive does contain of new product liability law is almost entirely substantive, calibrating balances of rights and liabilities between and among sellers and the consumers.<sup>139</sup> Responsibility for procedural matters, except for joint and several liability and time limits for claims, remains with the individual members of the Community.

Concern with state sovereignty appeared in provisions on the substance of product liability law. Thus, the Directive's failure to speak to important issues of procedural reform was no surprise.<sup>140</sup> Yet, this failure to develop rules governing the conduct of litigation—as well as the allowable derogations from the liability rules that *were* adopted—reduces one's confidence in the Directive's ability to secure the consistency of treatment of similarly situated plaintiffs that is essential to justice.<sup>141</sup> The Directive is nonetheless an important first step towards a streamlined and mature system of product liability, and it deserves the praise and the detailed treatment that it continues to draw.<sup>142</sup>

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139. The Directive does distinguish between producers and nonproducing suppliers. Directive, *supra* note 3, art. 3. As we will see, however, the Directive is much less helpful when it comes to distinguish the other players. The developed domestic law concerning third parties, buyers, and users did not find its way into the Directive. Nor does the Directive take a position on the rights of bystanders. By the Directive's terms, "consumers" are the protected class. But "[o]ne remarkable rather lacuna in the Directive is its failure to define the crucial term 'consumer.'" Shapo, *supra* note 107, at 283.

140. At least one commentator has accepted this frustrating lack of completeness in the Directive by pointing out that gaining acceptance of the central principle of strict liability ("la responsabilité objective") meant deferring other knotty questions until a later date ("rélegue toutes les autres questions au second plan"). Taschner, *supra* note 75, at 258.

141. See HODGES, *supra* note 16, at 13 ("In the absence of either approximation or harmonisation . . . it can hardly be said that a level playing field has in fact been created for the marketing of goods throughout the Community.").

142. See, e.g., Whittaker, *supra* note 107; Thomas Greer, *Product Liability in the European Economic Community: The New Situation*, SUMMER J. INT'L BUS. STUD. 337 (1989); Patrick Thieffry et al., *Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374*, 25 TORT AND INS. L.J. 65 (1989).

Detailed analyses of the Directive's articles have already been expertly accomplished.<sup>143</sup> My purpose is to develop some central themes that recur throughout the Directive. Doing so here enables later comparison with the more firmly established American doctrine and provides the basis for the case analyses in Part V.

### 1. *The Underlying Philosophy of the Directive*

Unlike modern American law, which at least at the national level shows a self-conscious tendency to be accompanied by useful analysis,<sup>144</sup> the European Union's Directives are usually bereft of significant textual or extra-textual explanation.<sup>145</sup> The Product Liability Directive is no exception. However, as explained in the preceding section, we can glean—from the protracted debates that preceded the Directive's promulgation—a fundamental tension between adherents of true strict liability and those who believed that negligence principles should retain their hold, at least to the extent of offering an affirmative defense for development risks.<sup>146</sup> The drafters' compromises over limiting damages are also a matter of record,<sup>147</sup> as are acknowledgments that the Directive falls short of its stated goal of uniformity.<sup>148</sup>

Nonetheless, the Directive is surprisingly silent on unifying philosophy. It does appear true that "the key informing principle [is] . . . consumer protection,"<sup>149</sup> and consumer protection language suffuses the Preamble.<sup>150</sup> Nonetheless, that same Preamble, where one might

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143. The best among these analyses is by Whittaker, *supra* note 107.

144. MUPLA is itself a good example of this approach. Especially when the statute at hand carries no weight of its own, such accompanying analyses can provide justifications for the chosen approach.

145. Whittaker, *supra* note 107, at 236-38. See, e.g., Council Directive 87/357 on products which, appearing to be other than they are, endanger the health or safety of consumers, 1987 O.J. (L 192) 49; Council Directive 89/391 regarding measures to encourage improvements in the safety and health of workers at work, 1989 O.J. (L 183) 1; Council Directive 93/43 on hygiene of foodstuffs, 1993 O.J. (L 175) 1.

146. See *supra* subpart III.A.2.

147. See *supra* subpart III.A.2.

148. See, e.g., HODGES, *supra* note 16, at 13-14; Thieffry et al., *supra* note 142, at 226.

149. Shapo, *supra* note 107, at 328.

150. That protection of the consumer is regarded as an animating principle of the Directive is borne out by the numerous references to the term "consumer protection" in the Preamble, in both general and specific situations. As to the general comments, the Preamble begins by stating that a primary concern of the Directive is to ensure that consumers not receive "differing degree[s] of protection," suggesting that consumers had previously been relegated to the protections provided by the individual states. Directive, *supra* note 3, pmbl., para. 2. Later, it is stated that the Directive's goal is "to protect the physical well-being and property of the consumer." *Id.* pmbl., para. 7. More specific concerns are

expect to find justification for the Directive's policy choices, is curiously short on explanation, even as to the central goal of consumer protection. Grand statements such as "liability without fault on the part of the producer is the sole means of adequately solving the problem . . . of a fair apportionment of the risks inherent . . . in production" need support, even more so since the Directive falls short of actually imposing "liability without fault."<sup>151</sup>

The absence of defining philosophy is still more glaring once one moves beyond the Directive's animating principle to its specific and general provisions. The Preamble does little more than serve as a kind of throat-clearing, complete with abundant "whereas" clauses.<sup>152</sup> Justifications external to the Directive itself are absent.

For example, it was decided, that the legal regime established by the Directive would *supplement* national laws affording protection to product-injured consumers.<sup>153</sup> That decision may or may not have been a good one. Facially, it is at odds with the announced goal of uniformity and would presumably allow continued forum-shopping to secure the most favorable slate of liability rules. Yet, such a sacrifice may have been demanded by the strong residuum of national interests resisting total replacement of established local law.<sup>154</sup> In either case, the Preamble's unadorned statement that claims "based on grounds of contractual liability or non-contractual liability . . . under the legal systems of the member states . . . should remain unaffected by this directive" is unhelpful.<sup>155</sup>

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voiced in a host of contexts. For example, it is stated that "protection of the consumer requires that all producers involved in the production process should be liable" thus affording the consumer the opportunity to pursue a claim against the most convenient entity. *Id.*, pmbl., para. 5. Joint and several liability is also called for because the "protection of the consumer requires . . . full compensation for the damage from any one of [the several persons liable]." *Id.* pmbl., para. 6. This concern for "the protection of the consumer requires that the liability of the producer remains unaffected [sic] by acts or omissions of other persons having contributed to cause the damage." *Id.* pmbl., para. 10. Lastly, "to achieve effective protection of consumers, no contractual derogation should be permitted" to relieve the seller from liability. *Id.* pmbl., para. 13.

151. *Id.* pmbl., para. 3. A similar criticism could be made of the Directive's concern with "distort[ion of] competition and . . . the movement of goods within the common market." *Id.* pmbl., para. 2. Does this argue for a regime favorable to plaintiffs or one that would reduce corporate costs? Competition might be distorted by unequal rules among member states, but in which direction should the legal regime push?

152. It is interesting to note that this device owes a great debt to the structure of French decisional law, which, as noted *supra* in subpart II.A, is notably deficient in underlying rationale. See DAWSON, *supra* note 21, at 407.

153. Directive, *supra* note 3, art. 13. See Shapo, *supra* note 107, at 323.

154. See Taschner, *supra* note 75, at 258.

155. Directive, *supra* note 3, pmbl., para. 14.

It may be that, lacking a well-developed body of product liability law against which to assess the Directive, its drafters did not feel compelled to offer much by way of overarching rationale; after all, instantiation of a uniform principle of strict liability represents a watershed development. That done, the bulk of the Directive can in one sense be seen as an elaboration of that principle, and of the kernel truth that the product-injured consumer should be compensated for injuries caused by defective products.

This Article therefore takes a two-part approach to the Directive. The remarks that follow represent one explanation of the language of the Directive and can be seen, in part, as furnishing the analytical notes that might have accompanied the express articles. In Part V, I apply the Directive's commands to decided cases. This exercise awaits the analysis of parallel developments in the United States in Part IV, so as to enable a side-by-side comparison, along with suggestions for the fair and coherent treatment of product liability law.

## 2. *Defining Defect and Fixing the Standard of Liability*

"The producer shall be liable for damage caused by a defect in his product"—Directive, Article 1.<sup>156</sup>

By placing this simple sentence at the top of the Directive, the drafters meant to convey a strong, clear message: liability for defective products was to be strict. But the signal is actually less clear than that, inviting speculation that the Directive hedges even on its fundamental premise. The Preamble states that "liability *without fault* . . . is the sole means of adequately solving the problem . . . of the risks inherent in modern technological production."<sup>157</sup> Thus, while Article 1's liability language is inferentially strict, it is odd that the term "without fault" does not repeat itself. Perhaps the difference was overlooked by the drafters (which I find unlikely), or it may have been that Article 1 was seen as unambiguous enough. After all, no language of "fault" appears within its one simple sentence.

It seems more likely that omission of strict liability language is a way of emphasizing that a finding of *defect* is necessary for liability.<sup>158</sup>

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156. *Id.* art. 1.

157. *Id.* pmbl., para. 3 (emphasis added).

158. Reference to causation also appears in Article 1. *Id.* arts. 1, 4. Of course, the requirement of causation is nearly universal in tort law. But codification of the causation requirement may preclude innovative judicial developments such as market share liability, in which plaintiff need not link injury to a specific defendant. See *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989), in which the court applied the market share liability in

As is true of the Model Act, and of legislation among the United States, the definition of defect comprehends a more searching analysis than would be demanded under a "true" strict liability regime. Article 6, entitled "Defective Product," ties defect to consumer expectation: "A product is defective when it does not provide the safety which a person is entitled to expect . . . ."<sup>159</sup> In reaching its conclusion on the issue, the court is to take "all circumstances into account."<sup>160</sup> The most significant of these are explicitly set forth in the Directive: "(a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; [and] (c) the time when the product is put into circulation."<sup>161</sup>

Particularly in its general introductory language and in subsection (a), the Directive looks suspiciously like the consumer expectation test that has been a part of American product liability jurisprudence since its inception. As I explain in subpart IV.B.1(a), *infra*, the consumer expectation test was decidedly rejected in MUPLA and has been generally disfavored among reformers. Instead, the consistent approach of choice has been the risk-utility test,<sup>162</sup> whereby the prod-

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the DES context, and extended the concept logically: "[T]here should be no exculpation of a defendant who, although a member of the market producing DES for pregnancy use, appears not to have caused a particular plaintiff's injury." *Id.* at 1078.

The language of Article 1 does seem to rule out market share liability in stating that the damage must be "caused by a defect in *his* [the producer's] product," as opposed to defects in the class of products. Directive, *supra* note 3, art. 1 (emphasis added).

159. Directive, *supra* note 3, art. 6.

160. *Id.* § 1.

161. *Id.* The article also contains a second subsection, which disables a court from finding defect "for the sole reason that a better product was subsequently put into circulation." *Id.* art. 6, § 2.

162. It might be argued that the test for defect under Article 6 allows room for consideration of a risk-utility type of approach. Article 6, § 1(c), which demands consideration of "the time when the product was put into circulation," may provide the entering wedge for such an approach. *Id.* art. 6, § 1(c). Since this factor seems concerned with what the manufacturer could have done at a particular time, one might argue that a reasoned assessment of risks and utilities be given weight. This argument should receive limited weight, if it makes sense at all. Subsection 1(c), after all, is one of the factors to be considered under the general pronouncement that defectiveness is defined by "the safety which a person is entitled to expect," so we are brought, full circle, back to the consumer expectation paradigm. *Id.* art. 6, § 1(c). Certainly, even if a court operating under the Directive were to allow some consideration of the risks and utilities of the product, the language of Article 6 demands that such an inquiry be in service of the consumer expectation analysis. And there is surely no room under the Directive for the either/or approach taken by some domestic courts, under which the tests are formally separated, and the plaintiff can recover by proving defect under either one. *See, e.g.,* *Barker v. Lull Eng'g, Inc.*, 573 P.2d 443 (Cal. 1978); *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871 (Alaska 1979); *Palmer v. Avco Distrib. Corp.*, 412 N.E.2d 959 (Ill. 1978).

uct's defectiveness *vel non* is assessed through a balancing of its use and its potential perils.<sup>163</sup>

Nonetheless, focus on the product's presentation makes eminent sense. Those cases involving the consumer who legitimately claims disappointed expectation entail, explicitly or implicitly, a course of communications and representations on the part of the product seller that induces justifiable reliance on product safety.<sup>164</sup> Having created

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163. MUPLA adopts this approach in section 104(B)(1). See discussion *infra* subpart IV.B.1(a). See also Henderson & Twerski, *supra* note 2, at 1532-34. Henderson and Twerski follow the lead of most courts and commentators, who consistently fix their attention on the balancing required by the risk-utility calculus. For a small sampling of cases and articles employing or recommending these tests in one variation or another, see *Barker v. Lull*, 573 P.2d at 443 (setting forth an "either/or" choice of reasonable consumer expectation or risk-utility tests); *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871 (Alaska 1979); *Dart v. Wiebe Mfg. Inc.*, 709 P.2d 876 (Ariz. 1985); *Seattle-First Nat'l Bank v. Tabert*, 542 P.2d 774 (Wash. 1975); John Wade, *On the Nature of Strict Tort Liability for Products*, 44 *MISS. L.J.* 825 (1973); Page Keeton, *Product Liability and the Meaning of Defect*, 5 *Sr. MARY'S L.J.* 30 (1973). But see Richard A. Epstein, *The Risks of Risk/Utility*, 48 *OHIO ST. L.J.* 469 (1987) (criticizing the approach, and suggesting a return to the latent-patent distinction). The proposed Restatement (Third) of Torts follows the same line of thinking, but places the burden on the plaintiff to prove the risks "could have been reduced by the adoption of a reasonable alternative design." *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 2 (Proposed Draft 1994).

Interestingly, Henderson and Twerski retain a place for consumer expectations: "[E]ven courts that apply a consumer-expectation test rarely do so without tempering it with significant risk-utility balancing. Consumer expectations are at the very least one factor to work into a risk-utility analysis. . . . As long as risk-utility standards are part of the mix, whether courts characterize the test for defect as risk-utility or consumer-expectation is of relatively minor importance." Henderson & Twerski, *supra* note 2, at 1533-34.

The ascendancy of the risk-utility test should be seen as the result of the way product liability law has developed domestically. Once courts came to recognize that products could be defectively designed, as well as defectively constructed, a novel method of assessing defect seemed called for. In my view, risk-utility can supplement the consumer expectation test in certain cases, but the latter model is usually preferable.

164. As Justice Traynor noted in *Greenman v. Yuba Power Products, Inc.*, "implicit in [a product's] presence on the market [is] a representation that it [will] safely do the jobs for which it was built." 377 P.2d 897, 901 (Cal. 1962). Professor Marshall Shapo has long and persuasively argued that questions of liability for defective products could be illuminated by paying sufficient attention to the representations made by product sellers. Shapo, *supra* note 107, at 291-92 (applauding the emphasis on "the presentation of the product," as admitting a broad range of readings that capture the complexities of the marketing, promotion, and actual appearance of the product). Professor Shapo first drew attention to the significance of product portrayal two decades ago. Shapo, *supra* note 11. More recently, I have argued that representational notions can profitably be applied to other areas of tort, including professional malpractice. See John G. Culhane, *Reinvigorating Educational Malpractice Claims: A Representational Focus*, 67 *WASH. L. REV.* 349 (1992). There, I suggested that one limitation on representational notions is that the injured party must be provided with enough information to act. *Id.* at 385. If not, the focus shifts to the plaintiff's forced reliance on the defendant. The same could be said of products that the "consumer" does not even know he is encountering, such as with asbestos, and with toxic



those expectations, the seller should not be heard to complain when the consumer suffers injury because those same expectations have not been fulfilled.

Although resort to the Preamble is once again required, the Directive imagines the inquiry into consumer expectation as "product-wide," not as an analysis of whether *this* consumer's expectations of safety were met: "[T]he defectiveness of the product should be determined not by its fitness for use but to the lack of the safety which *the public at large* is entitled to expect . . . ."<sup>165</sup> Yet the language is flexible enough to allow recovery to a consumer whose assurances of safety, through direct promotion and sale by the producer, are greater than that of other users of the same product. It might be said that any member of "the public at large" in such a situation would be "entitled to expect" a greater level of safety.<sup>166</sup>

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exposures more generally. Owing to the plaintiff's utter helplessness in many of these cases, the argument for recovery is strengthened, not diminished. This result is underscored under a consumer expectation model, which values the citizen's reasonable expectation that he is not the unwitting victim of whatever dangerous product the manufacturer drops into the market. A risk-utility test might yield a different result.

165. Directive, *supra* note 3, pmbl., para. 7 (emphasis added). It may be difficult, however, to gauge the reasonable expectation of consumers across national lines: "The European Community comprises . . . countries with varying economic and social traditions and values. Is it realistic to assume that a German or Danish consumer has the same values as a Greek, Spanish or Portuguese one?" HOWELLS, *supra* note 16, at 11. As Professor Quine has pointed out in the context of philosophy of language, the problems of individual translation appear both across language borders, Willard VanOrman Quine, *Translation and Meaning*, in *WORD AND OBJECT* 26-72 (1964), and even between speakers of the same language, in the same community. *Id.* at 79. Thus, in order to avoid complete solipsism, consumer expectation should be assessed by reference to the objectively reasonable person, as determined by the trier of fact, usually, the judge. Of course, such determinations will naturally be infused with the judge's own view of the consumer's expectation, a view shaped by the particular community in which she sits.

166. Whether the reasonable expectations of the individual consumer may be taken into account has been the subject of some discussion. Professor Shapo believes that the language of Article 6 allows "a potentially subjective interpretation centering on individual claimants." Shapo, *supra* note 107, at 293. In light of the Preamble, though, I read Article 6's phrase "the safety a person is entitled to expect" as disapproving of a wholly subjective analysis. Although the Directive's use of terms such as "person" and "consumer" seems somewhat haphazard, the expression "*the injured person*" is used in Article 8, section 2, which speaks to the plaintiff-specific issue of contributory negligence. Thus, it seems that use of the indefinite article ("*a person*") in Article 6 is deliberately more general, referring to any (and all) person. This reading is bolstered by the language of the Preamble, as well as by Dr. Taschner's view that the issue is "what the community as a whole considers to be right." Hans C. Taschner, *Product Liability in Europe: Future Prospects*, in *EEC STRICT LIABILITY IN 1992: THE NEW PRODUCT LIABILITY RULES* 83, 89 (PLI Litig. and Admin. Practice Course Handbook Series No. 371, 1988). Dr. Taschner was "a leading figure in the drafting of the Directive." Shapo, *supra* note 107, at 293. Dr. Taschner's view is not

Article 6 recognizes that product defect cases run along a long line between those involving the truly helpless and the foolhardy consumer. The article's defect standard is sufficiently flexible to accommodate this broad range of cases since "all circumstances" are taken into account. Thus, the unsuspecting victim of a manufacturing defect would have the strongest case, while one who knowingly encountered a dangerous feature of a product would likely have difficulty establishing that he or she was "entitled to expect" the product to be safe for that purpose. Wisely, the article does not anticipate the result in truly hard cases. The seller of a child's toy, for example, might be accountable for a defect that might be obvious to anyone *but* a child.<sup>167</sup>

This last possibility is supported by subsection 1(b) of Article 6 under which considers the producer's reasonable expectations as to a product's use. The wording of this section suggests that the inquiry is not whether the consumer has used the product reasonably,<sup>168</sup> but whether the misuse could reasonably be anticipated by the producer. For example, depending on the circumstances attending sale, a press manufactured with a removable safety guard might be considered defective if the injurious use might have been anticipated and prevented.<sup>169</sup> The lingering requirement that the use be "reasonably . . . expected" stands against truly bizarre arguments, such as claims that

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inconsistent with my own: what would the public at large consider to "be right" based on the representations that were actually made to this consumer?

167. In Part V, *infra*, I discuss a slate of cases arising along this continuum. The point here is just that, as a general matter, the complexities of product defect cases require a flexible approach. This conclusion has not gone unchallenged. Richard Epstein, for example, has argued that a bright-line rule is needed, allowing recovery in latent defect cases, but denying it in cases where the defect is patent. Epstein, *supra* note 163, at 469. In the course of a more general argument for clear tests, Epstein argues that making the liability determination on the basis of latent versus patent "as a rule of thumb . . . gives a clear, cheap, and correct answer in most cases. The distribution of cases along the latent/patent axis is such that there are few cases when the line between latent and patent is in doubt." *Id.* at 474. If this premise were true, one might agree with his conclusion. But the more complex model of product representation and portrayal better captures the range of cases. Simplicity is beguiling; unfortunately, justice is not simple. The examples in Part V, *infra*, make this point graphically. For elaboration of the powerful position advanced by Professor Shapo back in 1974, see generally Shapo, *supra* note 11.

168. That question is, and should be, a proper focus for the court. Under Article 8, section 2, a user's own negligence ("fault") in using the product reduces recovery. Directive, *supra* note 3, art. 8, § 2.

169. As a rule, such cases turn on the foreseeability of the modification or alteration to the manufacturer at the time of sale. See *Sheldon v. West Bend Equip. Corp.*, 718 F.2d 603 (3d Cir. 1983) (safety chains and bumpers had been removed from a man-lift; foreseeability was a jury question); *Kuziw v. Lake Eng'g Co.*, 586 F.2d 33 (7th Cir. 1978) (steel ram cover had been removed while machine was in operation; jury properly held manufacturer liable for foreseeable alteration when the only way to clean the machine was to remove

power lawn mowers are defective because the plaintiff has been injured using one to trim hair—either his own or someone else's.<sup>170</sup> Again, these issues are interwoven with issues of product presentation because for what a manufacturer might reasonably expect is often tied to how the product appears and is marketed.

### 3. *Note on the Relation between Defect and Failure to Warn*

Although the Directive does not specifically address the problem of defective warning, its focus on the "packaging" of the product can also illuminate the warning issue. In Part IV, *infra*, I offer a detailed analysis of the problem under MUPLA, referring to its response to some of the specific difficulties that arise in the arena of absent or inadequate warnings. For present purposes, I note that the Directive's emphasis on product presentation should also sweep in warnings.<sup>171</sup> This approach is consistent with the tendency of state courts to find a product defectively designed *because* it is unaccompanied by a proper warning. Thus, telling the product's story requires attention to its parts, to its warnings, and to all the details of its marketing.

In one sense, then, the inquiry into product defect subsumes the warning question. In one illustrative case, a court<sup>172</sup> had to decide whether a pool was defective because its shallow bottom was improperly lined, or because it was unaccompanied by sufficient warnings of its short depth.<sup>173</sup> By keeping the focus on the product's overall presentation, the Directive's approach might avoid unnecessary dissection of defective claims.<sup>174</sup>

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this cover); *Robinson v. Reed-Prentice*, 403 N.E.2d 440 (N.Y. 1980) (manufacturer was not liable when plaintiff's employer had cut a hole in the plastic safety gate).

170. The ever-present causation requirement, embodied in both Articles 1 and 4, also protects manufacturers against meritless suits of this sort. The cause of the plaintiff's injury in such unusual cases is not the product at all, but the plaintiff's own conduct.

171. This point has been made elsewhere; not the least significant of these comments has come from Dr. Taschner, one of the drafters of the Directive. See Taschner, *supra* note 75, at 95-96. Shapo seems to share this view. Shapo, *supra* note 107, at 306.

172. Courts, not juries, will usually do the fact-finding in European courts. Professor Shapo has offered some insight concerning the potential significance of this difference in interpreting the Directive. Shapo, *supra* note 107, at 293.

173. This example is provided by the case of *O'Brien v. Muskin Corp.*, 463 A.2d 298 (N.J. 1983). In that case, the warning not to dive was only 1/2 inch high. *Id.* at 302. The design defect issue concerned whether the vinyl lining that was used on the pool's bottom was as safe as a rubber latex lining would have been, and if not, whether plaintiff could be barred from suing on the ground that no other manufacturer of above-ground pools used rubber latex as lining. *Id.*

174. Omitted here is a separate discussion of subsection (c) of section 1, which takes into account "the time when the product was put into circulation." Directive, *supra* note 3,

Of course, the Directive can be criticized for its agnostic stance on several issues specific to the duty to warn that have plagued American courts for years. Among these are questions such as whether the so-called "sophisticated user" defense will be recognized for cases arising in the workplace setting<sup>175</sup> and whether any postsale duty to warn might attach. These issues are addressed by MUPLA, which has had a far greater wealth of case law to draw upon in reaching its conclusions. I therefore defer consideration of these issues until subpart IV.B.1(a), *infra*.

#### 4. Liability of Nonmanufacturing Sellers

Article 3 of the Directive houses the list, and speaks to the liabilities, of product-selling defendants. Under section 1 of that article, liability attaches to any "producer." By this, the Directive drafters meant to denote not only the entity that American courts have dubbed "manufacturer," but also those who make a raw material or any component part that finds its way into the finished product.<sup>176</sup>

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art. 6, § 1(c). This factor might support liability for failing to recall a product that was subsequently determined to pose a great danger, even if liability might not attach for the initial sale. Since the Directive is also silent on the issue of recall, speculation is all we have. For a discussion of MUPLA's treatment of the recall issue, see *infra* subpart IV.B.1(c).

175. The term "sophisticated user" is generally used in workplace cases, where the issue is whether the manufacturer can escape liability by communicating a warning to the employer, who is then expected to pass the information on to the workers. Some courts have adopted a bright-line, "no duty" approach, holding that it is sufficient to warn the employer. See, e.g., *York v. Union Carbide Corp.*, 586 N.E.2d 861 (Ind. App. 1992); *Rusin v. Glendale Optical Co.*, 805 F.2d 650 (6th Cir. 1986). This approach has been justified by the "difficulty of warning the individual employees, and because of the reasonableness of relying on the purchaser to protect his employees." DAVID A. FISCHER AND WILLIAM POWERS, *PRODUCTS LIABILITY, CASES AND MATERIALS* 403 (2d ed. 1994). The opposing school of thought regards the issue of warning in the workplace context as amenable to the same reasonableness analysis as is used in other cases alleging failure to warn. See RESTATEMENT (SECOND) OF TORTS § 388 (1966). For cases employing this approach, see *Adkins v. GAF Corp.*, 923 F.2d 1225 (6th Cir. 1991); *O'Neal v. Celanese Corp.*, 10 F.3d 249 (4th Cir. 1993); *Kennedy v. Mobay Corp.*, 601 A.2d 123 (Md. 1992); *Little v. Liquid Aid Corp.*, 952 F.2d 841 (5th Cir. 1992) (distinguishing "bulk seller" doctrine). See generally, Kenneth M. Willner, Note, *Failures to Warn and the Sophisticated User Defense*, 74 VA. L. REV. 579 (1988), which describes defenses to actions arising out of industrial accidents, compares the "duty" approach with the "Restatement" approach, and argues that some courts have used a "mixed" approach.

176. Directive, *supra* note 3, art. 3. Article 7, which lists defenses to liability, provides an escape from liability for component (and presumably raw material) sellers whose product is itself unobjectionable. Where the alleged defect "is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product," the component manufacturer is exculpated. *Id.* art. 7(f). This sensible rule, implicitly recognizing that liability without defect is incoherent, is echoed by

Of greater significance for American product liability scholars and courts is the Directive's bold stand on two classes of sellers that have mostly avoided notice in the United States: importers and those who somehow present themselves as producers. Both of these are defined as producers and consequently are liable whenever manufacturers are.

Particularly with reference to those who hold themselves out as producers, the Directive's representational bias again emerges. The Directive treats as a producer "any person who, by putting his name, trademark or other distinguishing feature on the product *presents himself* as its producer."<sup>177</sup>

As to importers, the Directive's treatment reflects both its underlying philosophy of consumer protection and its consistent emphasis on the course of communications between buyer and seller. First, allowing the injured plaintiff an avenue of recovery against the importer may allow problems of jurisdiction to be surmounted, thereby maximizing the chances of finding an available defendant.<sup>178</sup>

Second, the drafters presumably recognized that, as far as many consumers would be concerned, the importer would seem to be the manufacturer. At least, the importer (or its retailer, for example) is the entity to which the consumer would complain if the product did

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American courts. *See, e.g.,* Wiler v. Firestone Tire & Rubber Co., 95 Cal. App. 3d 621, 157 Cal. Rptr. 248 (1979) (no strict liability on component part manufacturer where the component is itself without defect). *Cf. Feuerverger v. Hobart Corp.*, 738 F. Supp. 76 (E.D.N.Y. 1990) (component part manufacturer liable if it supplies *defective part* which causes accident); DeLeon v. Commercial Mfg. & Supply Co., 148 Cal. App. 3d 336, 195 Cal. Rptr. 867 (1983) (component part manufacturer not absolved of liability where it was foreseeable that design of component part could pose a hazard when utilized as a part of the whole machinery).

177. Directive, *supra* note 3, art. 3, § 1. This approach is not without precedent in the American courts. *See* Torres v. Goodyear Tire & Rubber Co., 901 F.2d 750, 751 (9th Cir. 1990) (holding that strict product liability applies to trademark licensors who "significantly participate in the overall process by which the product reaches consumers"). This theory focuses on the fact that trademark holders have the power and ability to "shape the destiny of products, both as to form and manner of presentation to the public." Shapo, *supra* note 107, at 286. *See generally* Holly Piehler Rockwell, Annotation, *Trademark Licensor's Liability for Injury or Death Allegedly Due to Defect in Licensed Product*, 90 A.L.R. 4th 981 (1991). *See also* RESTATEMENT (SECOND) OF TORTS § 400 (1977) ("One who puts out as his own product a chattel manufactured by another is subject to the same liability as though he were its manufacturer.").

178. For obvious reasons, the importer is treated as an additional producer; the actual manufacturer is on the hook as well. Article 3, section 2 imposes liability on importers "without prejudice to the liability of the producer." Directive, *supra* note 3, art. 3, § 2. By the terms of Article 5, liability, where proper against multiple defendants, is joint and several. *Id.* art. 5.

not perform as expected. Therefore, it also appears sensible to require the importer to stand behind the product when personal injury strikes. Indeed, a developing body of case law suggests that American courts are moving in this direction too.<sup>179</sup>

A less definitive result applies with respect to those sellers who do not qualify as producers. The Directive refers to all such sellers as "suppliers."<sup>180</sup> By and large, suppliers consist of those who are "middle sellers" of products, such as distributors and retailers.<sup>181</sup> As developed in subpart IV.B.1(b), *infra*, the American judicial and statutory law have been inconsistent as to their liability. The Directive attempts yet another solution: by the terms of Article 3, section 3, all suppliers are treated as producers unless they "inform . . . the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product."

This approach approximates the trend in domestic law, whereby nonmanufacturing sellers are often cast in the role of guarantors, standing by to provide compensation where the manufacturer is unable.<sup>182</sup> The Directive's approach, however, is more restrictive than the average state statute, which would allow supplier liability when the manufacturer is not available for *any* reason, most typically insolvency. The Directive simply requires the supplier to do a bit of detective work, to unmask the producer.<sup>183</sup> That done, the supplier is exculpated, presumably even if the producer no longer exists.

To the extent that the Directive walls off recovery against suppliers, it may betray its promise of consumer protection based on reason-

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179. See, e.g., *Hapner v. Rolf Brauchli, Inc.*, 273 N.W.2d 822, 823 (Mich. 1978) (while the court found that this defendant importer did not have sufficient "minimum contacts" with the forum to support jurisdiction, the court held that "[a] manufacturer's marketing system is generally seen as a purposeful avilment of the . . . forum in which it has reason to know its products are distributed pursuant to that [marketing] system"); *Seattle-First Nat'l Bank v. Tabert*, 542 P.2d 774 (Wash. 1975) (upholding imposition of strict liability upon an automobile importer, focusing on the role of the importer in the marketing of the product).

180. Directive, *supra* note 3, art. 3, § 3.

181. The term "supplier" is nowhere defined in the Directive. As has been recognized, however, the context in which the term is used makes clear that the drafters had in mind all sellers who do not fit the definition of producer. See Whittaker, *supra* note 107, at 268-70.

182. See *infra* subpart IV.B.1(b). I have treated this issue in detail in John G. Culhane, *Real and Imagined Effects of Statutes Restricting the Liability of Nonmanufacturing Sellers of Defective Products*, 95 DICK. L. REV. 287 (1991).

183. The same section also makes clear that, at least insofar as importers are concerned, they are to be treated *exactly* like manufacturers. The rule as to suppliers "shall apply, in the case of an imported product, if this product does not indicate the identity of the importer even if the name of the producer is indicated." Directive, *supra* note 3, art. 3, § 3.

able expectation. As domestic courts have long recognized, middle sellers "are an integral part of the overall producing and marketing enterprises," and may "[i]n some cases . . . be the only member of [those enterprises] reasonably available to the injured plaintiff."<sup>184</sup> The Directive's approach is especially puzzling given its enlightened treatment of importer and "product presenter" liability. Indeed, to the extent that middle sellers, particularly retailers, are viewed by consumers as (re)presenting the product as safe, this penurious supplier liability rule seems at odds with these other consumer protective rules and perhaps even in conflict with the Directive's animating philosophy.

### 5. *Treatment of Problem Products*

As is developed in subpart IV.A, *infra*, American product liability law has been in active development for nearly a century. Thus, a mature body of judicial, statutory, and scholarly literature is at hand—a body that has expanded well beyond the basic issues involving the definition and classification of defect, the tension between strict liability and negligence, and the classes of proper plaintiffs and defendants. The courts have tackled a wealth of issues, including: unavoidably unsafe products,<sup>185</sup> postmanufacture changes in design,<sup>186</sup>

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184. *Vandermark v. Ford Motor Co.*, 391 P.2d 168, 171 (Cal. 1964).

185. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1966) (creating an exception to strict liability for "unavoidably unsafe" products which are otherwise properly prepared and accompanied by proper directions and warnings. This exception has been held to apply to certain drugs, vaccines, and asbestos). See, e.g., *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121 (9th Cir. 1968) (holding that there was a duty to warn of an extremely minimal risk of contracting polio from a polio vaccine); *Kearl v. Lederle Lab.*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985), *disapproved in* *Brown v. Super. Ct.*, 751 P.2d 470 (Cal. 1988) (*Abbott Laboratories*) (holding that each prescription drug must be evaluated on its particular merits to determine if it is, in fact, "unavoidably unsafe"); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974) (the first asbestos case in which a plaintiff recovered damages based upon failure of the product manufacturer to warn workers of the dangers of asbestos).

186. See, e.g., *Young v. Aeroil Prods. Co.*, 248 F.2d 185 (9th Cir. 1957) (manufacturer not liable where decedent's employer had added additional equipment to an elevator, causing it to become unbalanced); *Soler v. Castmaster, Div. of H.P.M. Corp.*, 484 A.2d 1225 (N.J. 1984) (employer had made several modifications to a die casting machine; court held that although the original design of the machine could be found defective under a risk-utility analysis, it was a jury question whether the original defect was a proximate cause of the accident, regardless of the post-manufacture changes); *Brown v. United States Stove Co.*, 484 A.2d 1234 (N.J. 1984) (holding that extensive modifications to a heater and removal of its safety features was sufficient to release the manufacturer from liability).

the effect of compliance with "state of the art",<sup>187</sup> the effect of compliance with both mandatory design specifications,<sup>188</sup> and regulatory requirements.<sup>189</sup>

The comparatively embryonic European product defect law has not yet spawned sophisticated treatments of these issues. Nor does the Directive deal with most of the "problem" cases. Article 7, however, directly faces the two questions of compliance with mandatory regulations and the state of the art defense. While the Directive

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187. The issue is whether the manufacturer has a defense when the product is built or designed to the limits of available technological and other knowledge at the time of sale; according to one court, state of the art "includes all of the available knowledge on the subject at a given time, and this includes scientific, medical, engineering, and any other knowledge that may be available." *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 639 (Md. 1992) (quoting *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1164 (4th Cir. 1986)). For cases holding that state of the art is a defense, see *Bruce v. Martin Marietta Corp.*, 544 F.2d 442 (10th Cir. 1976); *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549 (Cal. 1991) (failure to warn case).

The other side is expressed by *O'Brien v. Muskin Corp.*, 463 A.2d 298 (N.J. 1983), discussed *supra* note 173. The court in *O'Brien* noted that "a product may embody the state of the art and still fail to satisfy the risk-utility equation. . . ." 463 A.2d at 305. In the wake of the *O'Brien* decision, the New Jersey legislature passed a new statute which provides that a seller shall not be liable if at the time the product was manufactured there was not a practical and technically feasible alternative design that would have prevented the harm without impairing the function of the product. N.J. STAT. ANN. § 2A:58C-3 (West 1987). The statute also provides that, if the court finds, on the basis of clear and convincing evidence, that the product is egregiously unsafe or has little or no usefulness, state of the art will not be a defense. *Id.*

188. Where a manufacturer builds to specifications required by the government, it can assert the "government contract defense." The Supreme Court, in *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988), set forth a defense by which manufacturers of military equipment could escape liability for design defect if "(1) the United States approved reasonably precise specifications; (2) the equipment conformed to those specifications; and (3) the supplier warned the United States about the dangers . . . known to the supplier but not to the United States." *Id.* at 512. The issue is less clear where the specifications have not been set forth by the government, but by private contract. Compare *Michalko v. Cooke Color and Chem. Co.*, 451 A.2d 179 (N.J. 1982) (holding that strict liability was appropriate notwithstanding construction according to specifications) with *Lesnefsky v. Fischer & Porter Co.*, 527 F. Supp. 951 (E.D. Pa. 1981) (holding to the contrary, except where the danger is obvious to the contractor building to specification).

189. *Stanton v. Astra Pharmaceutical Prods., Inc.*, 718 F.2d 553 (3d Cir. 1983) held that a manufacturer's failure to file certain reports regarding a drug in compliance with FDA regulations constituted negligence and that there was sufficient evidence to show causation between the failure to report and an injury caused by the drug. Even where there is compliance with a regulatory requirement, this is not always sufficient to protect the manufacturer from liability. In *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322 (Or. 1978), the court noted that an FAA regulation addressing design specifications for aircraft design was only a minimum standard, and compliance with that standard did not automatically shield the manufacturer from liability.



plainly states the rule as to each in plain language, interpretation of the impact of these sections is difficult.

With respect to compliance with mandatory regulations, Article 7(d) offers a defense to a producer who can show "that the defect is due to compliance of the product with mandatory regulations issued by the public authorities."<sup>190</sup> What exactly does this mean?

The domestic law has generally been careful to separate cases involving compliance with mandatory *design* from those involving products that are subject to *approval* by the relevant regulatory agency. The Directive's use of the term "mandatory regulations" thus creates an ambiguity: Did the drafters mean to foreclose suit only where a manufacturer built a product to specification, or more broadly, in any case where regulatory compliance was needed? If the latter interpretation holds, the number of cases would be drastically reduced. This is especially so because whatever national regulations apply are supplemented by a daunting battery of European Union directives, which impose safety requirements for vast classes of products.

It is probable that the drafters of the provision had in mind only those cases in which the producer followed design specifications. As Professor Whittaker has noted, the defense only applies "in the rare situation where the defect is *due to* compliance with [regulations]."<sup>191</sup> It would torture that language to argue, in the typical design defect case involving a product subject to regulatory requirements, that compliance with such requirement *caused* the defect. Usually, the producer is attempting to push the product past the regulators, not building to specification.

As to the state of the art issue, the Directive offers a defense—defeasible by member states—to producers who can show that at the time of production "the state of scientific and technical knowledge . . . was not such as to enable the existence of the defect to be discovered."<sup>192</sup> This very general formulation is unsatisfying to an American readership, familiar with the variations on this theme sounded by the judiciary and the legislature.<sup>193</sup> Yet, by using the terms "scientific and technical knowledge," the Directive makes clear that it will not suffice to invoke common trade practice or custom as a defense.<sup>194</sup> The lan-

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190. Directive, *supra* note 3, art. 7(d).

191. Whittaker, *supra* note 107, at 257 (emphasis added).

192. Directive, *supra* note 3, art. 7(e).

193. See *infra* subpart IV.B.1(c).

194. It has been suggested that a whole industry could be negligent in its scientific inquiry. Garey B. Spradley, *Defensive Use of State of the Art Evidence in Strict Products*

guage chosen also suggests that the defense will be applied sparingly. A producer can only stand behind the state of the art defense where available knowledge did not allow *discovery* of the defect. This standard is presumably more difficult to reach than one based on the possibility of *eliminating* the defect.

Let us consider one example where the distinction introduced above would make a difference. In the case of new drugs, injurious side effects are often not uncovered until well after the drug has come to market.<sup>195</sup> The Directive would not impose liability unless the manufacturer knew or, using available scientific information, could have known of the defect.<sup>196</sup> The Directive does not even seem to require a posted warning that the drug's possible effects are yet unknown, thereby reflecting silent agreement with MUPLA's treatment of the issue.<sup>197</sup>

On the other hand, if the dangers of the drug were known, but could not be eliminated, the Directive suggests that liability could be proper. In that case, the developmental risk defense would not be available and the liability issue would return to a section 106 analysis. Courts applying the Directive would do well to follow the approach taken by the Second Restatement of Torts, in comment k to section 402A. For such unavoidably unsafe products, liability would depend on whether the drug was "accompanied by a proper warning."<sup>198</sup> The Directive's emphasis on product presentation could handily accommodate such a focus.

## 6. Time Limitations on Actions

As outlined above, the Directive, although moving in a consumer-friendly direction on the substantive law of defective products, is mostly silent on matters of procedure; it apparently consigns treat-

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*Liability*, 67 MINN. L. REV. 343, 360-61 (1982) (citing Judge Hand in *The T.J. Hooper*, 69 F.2d 737, 740 (2d Cir. 1932), *cert. denied sub nom. Eastern Trans. Co. v. Northern Barge Corp.*, 287 U.S. 662 (1932)). This concern seems overstated because it requires the assumption that scientific *knowledge*—as opposed to actual practice—in an entire industry is being squelched. That seems unlikely.

195. One such drug may be tetracycline, which had a once unknown propensity to discolor teeth. *Feldman v. Lederle Lab.*, 608 A.2d 356 (N.J. Super. Ct. App. Div. 1992), *aff'd*, 625 A.2d 1066 (N.J. 1993).

196. Note that the Directive speaks in strict terms, allowing no escape for a manufacturer who can show reasonable diligence in attempting to keep up with scientific and technological developments. Of course, as demonstrated in Part II, *supra*, the European courts have been no less adept than our own in reinterpreting statutory language.

197. See *infra* subpart IV.B.1(c).

198. See *infra* subpart IV.B.1(c) for a fuller discussion of this point under MUPLA.

ment of such issues to local legislation.<sup>199</sup> In addition to the optional damage limitations set forth in Article 16,<sup>200</sup> the Directive speaks only to joint and several liability, which it expressly retains,<sup>201</sup> and to issues of limitation and repose.

Unfortunately, the Directive did not achieve a fully just result with respect to these matters. Article 10, which establishes a three-year statute of limitations, may be problematic. According to the language of that provision, the statute starts to run "from the day . . . the plaintiff becomes aware, or should reasonably have become aware, of the damage, the defect, and the identity of the producer."<sup>202</sup> The unanswered question here is whether the running of the statute will be delayed until the plaintiff can reasonably make the causal connection between product exposure and the injury.<sup>203</sup> The article should have made clearer the tie between "damage[,] defect, and the identity of the producer."<sup>204</sup> As discussed in detail *infra*, MUPLA makes this point much more cleanly.<sup>205</sup>

Worse yet is Article 11, which declares that "the rights conferred upon the injured person . . . shall be extinguished upon the expiration of a period of 10 years from the date on which the producer put [the product causing injury into circulation] unless the injured person has . . . instituted proceedings against the producer."<sup>206</sup> By its terms, this

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199. See *supra* subpart III.B.1.

200. See *supra* subpart III.A.2.

201. Directive, *supra* note 3, art. 5, provides: "Where, as a result of the provisions of this directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse." As pointed out in subpart IV.B.2, *infra*, I do not have much to say about these procedural choices, which represent more or less defensible political decisions.

202. Directive, *supra* note 3, art. 10.

203. Drugs posing long-term risks and toxic torts are obvious cases in which plaintiff may be unable, for a long period of time, to connect injury with responsible cause. As one commentator has eloquently stated: "[P]rescription drugs . . . contain unforeseeable risks due to interaction with the mysterious human body." Elizabeth C. Price, *Toward A Unified Theory of Products Liability: Reviving the Causative Concept of Fault*, 61 TENN. L. REV. 1277, 1332 (1994).

204. Professor Shapo believes that the Directive's language is sufficiently clear to answer this question: "In declaring that the plaintiff should reasonably be aware of the defect, the Directive settles an important and controversial issue in favor of claimants." Shapo, *supra* note 107, at 320. He then hedges his own bet, however, noting that in cases where the plaintiff knows of the harm, but not the cause, "arguably the requirement of knowledge of defect could be interpreted to include knowledge of causation." *Id.* (emphasis added).

205. See *infra* subpart V.A.

206. Directive, *supra* note 3, art. 11.

article provides no exceptions. The unfairness of this result is clear when the product is a drug which presents long-term hazards such as DES,<sup>207</sup> but the inequity should not go unnoticed when the product is made to be used safely for longer than ten years.<sup>208</sup>

The parallel provision of MUPLA, which also establishes a ten-year statute of repose, affords only a qualified presumption<sup>209</sup> that products causing injury beyond that time are safe. In subpart IV.B.2, *infra*, I argue that even such a qualified presumption is mistaken. A fortiori, then, a blanket rule against recovery is unjustified. As one court perceptively noted, there is injustice in barring a claim "before it ever existed."<sup>210</sup>

#### IV. Product Liability Law in the United States: History and Reform

The ebb and flow of product liability law in the United States has been dramatic within a remarkably brief period. Courts have moved from a position of virtually no recovery for those injured by defective products to a position approaching strict liability and finally to a less easily described middle position.<sup>211</sup> My purpose here is to outline these developments in just enough detail to allow appreciation of the context out of which the recent reform movement has grown.

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207. See, e.g., *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989), *cert. denied*, 493 U.S. 944 (1989); *Sindell v. Abbott Lab.*, 163 Cal Rptr. 132 (Cal. 1980), *cert. denied sub nom. E.R. Squibb & Sons, Inc. v. Sindell*, 449 U.S. 912 (1980). Even a more plaintiff-friendly approach to issues of repose will not necessarily allow these claims to go forward. The New York Court of Appeals has recently held that DES manufacturers have no duty to third-generation women whose injuries (allegedly) resulted from their premature birth, which were in turn said to have resulted from her mother's damaged reproductive system, all of which stemmed from the grandmother's ingestion of DES. *Enright v. Eli Lilly & Co.*, 570 N.E.2d 198 (N.Y. 1991), *cert. denied*, 502 U.S. 868 (1991). Should manufacturers of DES have foreseen that defective drugs taken by pregnant women could have ripple effects extending for two subsequent generations? Since the answer to that question is not self-evident, it seems the better approach would have been to allow the plaintiff to proceed with her case.

208. See *infra* subpart IV.B.2 (discussing this issue in the context of MUPLA).

209. MUPLA, *supra* note 1, § 110(B)(1) (general), (2) (exceptions).

210. *Diamond v. E.R. Squibb & Sons, Inc.*, 397 So. 2d 671, 672 (Fla. 1981), *quoted in Shapo, supra* note 107, at 322.

211. See generally RICHARD A. EPSTEIN, *CASES AND MATERIALS ON TORTS* 611-13 (5th ed. 1990).

### A. *The Development of Product Liability Law in the United States*

Until the early part of this century, courts lagged behind the technological and societal changes that enabled mass production of consumer goods. Mesmerized by the older paradigm of direct sales of individual goods from manufacturer to consumer-user, courts limited recovery for injury-causing defects to those who were in privity with their buyers.<sup>212</sup> As is made clear from a number of cases decided during the late nineteenth and early twentieth century, judicial self-deception in this regard was made more palatable by the fear that tracing liability to its proper source in mass-production cases would overburden both the court and the manufacturer.<sup>213</sup>

*MacPherson v. Buick Motor Co.*,<sup>214</sup> is deservedly a seminal case, both because the court discarded the out-of-touch privity rule, and because of Justice Cardozo's boldness in recognizing the rapid disappearance of the world in which the rule had developed. Anyone foreseeably injured by the negligence of the manufacturer should recover, and because most products were by this time mass-produced, the foreseeable class of plaintiffs might be quite large.<sup>215</sup>

Despite its importance, *MacPherson* itself did not materially assist the great number of product victims. Steadfast judicial adherence to the requirement of demonstrating negligence posed insuperable difficulties, in part because plaintiffs needed to show some problem with the manufacture of a defective product long after its assembly and sale.

Unwilling directly to drop the negligence requirement, courts exercised ingenuity by permitting that result to occur *de facto*. First, they increasingly relied on *res ipsa loquitur*, that much-reviled and ill-understood doctrine of circumstantial evidence, to presume that an injury-causing product was negligently manufactured.<sup>216</sup> Second, they

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212. *Huset v. J. I. Case Threshing Mach. Co.*, 120 F. 865 (8th Cir. 1903). The best known English case taking the same position is *Winterbottom v. Wright*, 152 Eng. Rep. 402 (Ex. 1842).

213. *Huset*, 120 F. at 867.

214. 111 N.E. 1050 (N.Y. 1916).

215. *Id.* at 1053-55.

216. The problems with using *res ipsa* in this context have been detailed elsewhere. See, e.g., EPSTEIN, *supra* note 211, at 246-47; JAMES A. HENDERSON, JR. & AARON D. TWERSKI, *PRODUCTS LIABILITY—PROBLEMS AND PROCESS* 18-25 (1987). The central difficulty, as I see it, is that in many cases it may stretch credulity to argue that the defect would "more likely than not" be traceable to negligence. There is also the issue of whether a defective product can ever be said to satisfy the requirement that the instrumentality causing the

increasingly allowed plaintiffs to use warranty law to achieve strict liability,<sup>217</sup> despite the reasonable argument that warranties were intended only to protect commercial and consumer purchasers from disappointed product expectations—not to provide a remedy for personal injury.<sup>218</sup> Eventually, courts further distorted warranty law by abandoning its foundation in the contract of sale: injured consumers were allowed to reach remote sellers as well.<sup>219</sup>

These developments having warped both negligence principles and warranty law, it was probably inevitable that courts would embrace strict liability in tort as the preferred theory of recovery for product defect. Appropriately, it fell to Justice Traynor, who had championed the cause of strict liability as far back as 1944, to announce the principle's delayed vindication: "To establish the manufacturer's liability it was sufficient [to prove injury from] using [the product] in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the [product] unsafe for its intended use."<sup>220</sup>

This triumph of the strict liability doctrine indicated judicial acceptance of its asserted justifications. Strict liability best protects the helpless consumer, in part by relieving her of the difficult burden of showing negligence; placing the cost on the party best able to bear it,

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injury be in the defendant's exclusive control. This problem is particularly acute in cases where the injury-causing product has been passed around outside the chain of distribution. In fact, this appears to have been a problem in *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436 (Cal. 1944), in which the exploding bottle that caused plaintiff's injury had been delivered to the restaurant in which she worked some 36 hours earlier. Who knows what might have happened to it between that time and her injury? The court nonetheless bottomed its affirmance of the verdict in favor of plaintiff on *res ipsa*, thereby triggering Justice Traynor's famous concurrence. There, he argued that liability should be strict, and that courts should simply acknowledge what they were in fact already doing by so attenuating the requirements of negligence. *Id.* at 440 (Traynor, J., concurring).

217. See *McCabe v. L.K. Liggett Drug Co.*, 112 N.E.2d 254 (Mass. 1953). See also *Mazetti v. Armour & Co.*, 135 P. 633 (Wash. 1913) (one of the first cases to suggest warranty as an alternative to proving negligence evidenced by the court's citing language referring to pureness, wholesomeness, and fitness).

218. Prosser referred to the warranty portion of products liability as "a freak hybrid born of the illicit intercourse of tort and contract." 1 MARSHALL S. SHAFQ, *THE LAW OF PRODUCTS LIABILITY* lxiii (2d ed. 1990) (quoting William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 800 (1966)).

219. *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960) (the case universally credited with abandoning the privity requirement in warranty cases).

220. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1962) (Plaintiff was using a tool known as the Shopsmith when he was struck in the head with a piece of flying wood inflicting serious injury. The Shopsmith was a combination power tool that could be used as a saw, drill, or lathe.).

either by purchasing insurance or by self-insuring and then distributing the costs fairly among consumers; and providing the maximum incentive for the manufacturer to create safe products, thereby minimizing the number of losses.<sup>221</sup>

It has been observed that strict liability took hold mostly in the context of manufacturing defects—problems in production that the product's creator did not intend and that occur only episodically. This is not entirely true. In *Greenman v. Yuba Power Products, Inc.*,<sup>222</sup> for example, it is unclear whether the defective set screws were a manufacturing defect or a design defect. The latter term is typically applied where a manufacturer's conscious design choice results in injury to consumers. Suits alleging defect design arise after the manufacturer has selected a mixture of utilities and risks and one of the built-in risks has materialized.

Justice Traynor was equivocal on the nature of the product's defect in *Greenman*, writing of a defect in "design and manufacture."<sup>223</sup> Nonetheless, it is fair to say that the product defect cases that arose before the 1970s generally involved latent defects. Thus, whether or not the manufacturer chose the risk to which the plaintiff was exposed, the plaintiff had no opportunity to screen the product for defect and, therefore, no real chance for self-protection. Additionally, it is unclear in these early cases whether the manufacturer necessarily recognized the danger to which the consumer was exposed. Even if the manufacturer of the defective combination power tool in *Greenman* allegedly chose to make the set screws of insufficient strength, did the manufacturer recognize that such a strength posed a risk of injury?

Although it may therefore be an oversimplification to state that all of the early strict liability cases involved manufacturing defects, it is fair to note that the products might have been universally deemed defective, and thus more dangerous than the consumer would expect. In *Greenman*, would any manufacturer consciously proceed, after a cost-benefit analysis, to produce such weak screws when stronger ones were available for a few pennies? Even if so, should the unsuspecting injured party be unable to recover damages?

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221. *Greenman* was followed quickly by § 402A of the Restatement (Second) of Torts (1965). This highly influential text almost immediately began to exercise a strong influence over courts and is at least partly responsible for the developments subsequent in product liability law to be discussed herein.

222. 377 P.2d at 898-99.

223. *Id.* at 901 (emphasis added).

Finding an answer to the latter question is made easier once we have tracked down the source of strict liability in these *Greenman*-era cases. That source is warranty law. The jury in these early strict liability cases was invited to consider whether the consumer's expectations as to safety were violated. Compare *Greenman* with a case such as *McCabe v. Liggett Drug Co.*,<sup>224</sup> arising under the older law of sales, in which the court tied an exploding coffee maker's breach of the warranty of merchantability to the plaintiff's use of the appliance in an ordinary manner.

Once established in the easier cases of latent defect and disappointed consumer expectation, strict liability mushroomed. Most courts expanded the cast of culpable defendants along the chain of a product's distribution, drawing in component part manufacturers,<sup>225</sup> and nonmanufacturing middle sellers, such as retailers,<sup>226</sup> wholesalers,<sup>227</sup> and distributors.<sup>228</sup> Lessors also found themselves liable.<sup>229</sup> These expansions have at least two sources. First, courts acknowledged that the manufacturer of the completed product may not always be available to the injured consumer or user, and that it might therefore be necessary to ensnare others in the product's chain of sale. Second, the recognition emerged that the sale of most products takes place through a complex web of distribution, and that sellers throughout that chain can arrange their contractual dealings to achieve the desired exposure to product liability.<sup>230</sup>

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224. 112 N.E.2d 254, 256 (Mass. 1953).

225. See, e.g., *Hiigel v. General Motors Corp.*, 544 P.2d 983 (Colo. 1975); *Suvada v. White Motor Co.*, 210 N.E.2d 182 (Ill. 1965), *overruled in part by* *Dixon v. Chicago & North W. Trans. Co.*, 661 N.E.2d 704 (Ill. 1992); *Mott v. Callahan AMS Machine Co.*, 416 A.2d 57 (Md. 1980). See also 1 AMERICAN LAW OF PRODUCTS LIABILITY 3d § 8:12 (1957). "Where there is no change in the component, and where the cause of harm or injury is found to be a defect in the component part, the maker and supplier of the defective component part may be held strictly liable in tort to the ultimate user or consumer." *Id.*

226. See, e.g., *Kroger Co. v. Goodhew*, 206 So. 2d 882 (Ala. 1968); *Newmark v. Gimbel's Inc.*, 258 A.2d 697 (N.J. 1969).

227. See, e.g., *Cottom v. McGuire Funeral Service, Inc.*, 262 A.2d 807 (D.C. 1970); *Bowman Biscuit Co. v. Hines*, 251 S.W.2d 153 (Tx. 1952).

228. See, e.g., *Canifax v. Hercules Powder Co.*, 46 Cal. Rptr. 552 (Cal. Ct. App. 1965); *Belcher v. Hamilton*, 475 S.W.2d. 483 (Ky. 1971).

229. See, e.g., *Becker v. IRM Corp.*, 698 P.2d 116 (Cal. 1985), *overruled in part by* *Peterson v. Super. Ct.*, 10 Cal. 4th 1185 (1995); *Cintrone v. Hertz Truck Leasing & Rental Serv.*, 212 A.2d 769 (N.J. 1965).

230. These justifications have not met with universal approval. For an analysis of the history of the liability of nonmanufacturing sellers, see *Culhane*, *supra* note 182, at 257-95.



Simultaneously, the class of proper plaintiffs grew to embrace users and bystanders.<sup>231</sup> Bizarre causal chains leading to product injury aside, such expansions were required by the principle of foreseeability. The obvious problem of applying a consumer expectation theory to a bystander is generally thought to be overborne by the bystander's more complete helplessness—of all parties, the bystander is best able to claim that she is a victim of a situation not of her own making.

The latter expansions can be accommodated within the framework of the latent defect-helpless consumer lawsuit detailed above. More troubling, at least to the current group of reformers, was the movement away from reliance on the consumer's expectation of product safety. Many courts, although by no means all, began to allow recovery even for patent defects based upon a balancing of the product's perceived risks against its benefits.<sup>232</sup>

This movement was brought about, at least in part, in response to a growing number of cases involving so-called patent defects. The patent danger rule had uniformly denied recovery to those who knew of a product's hazards: "[T]he manufacturer of [any product], dangerous because of the way in which it functions, and patently so, owes to those who use it a duty merely to make it free from latent defects and concealed dangers. [Plaintiff] must . . . prove the existence of a latent defect or [an unknown] danger. . . ."<sup>233</sup>

In the important case of *Micallef v. Miehle Co.*,<sup>234</sup> the New York Court of Appeals cheerfully abandoned the so-called patent danger rule, reasoning that the locus of inquiry should be on whether a *reasonably* designed product would have been safer. The court also quoted approvingly a Washington state case: "The law, we think, ought to discourage misdesign rather than encouraging it in its obvious form."<sup>235</sup>

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231. See, e.g., *Elmore v. American Motors Corp.*, 451 P.2d 84 (Cal. 1969); *Codling v. Paglia*, 298 N.E.2d 622 (N.Y. 1973).

232. See, e.g., *Palmer v. Massey-Ferguson*, 476 P.2d 713 (Wash. Ct. App. 1970); *Auburn Mach. Works Co., Inc. v. Jones*, 366 So. 2d 1167 (Fla. 1979).

233. *Campo v. Scofield*, 95 N.E.2d 802, 803 (N.Y. 1950), *overruled in part by Micallef v. Miehle Co.*, 348 N.E.2d 571 (N.Y. 1976).

234. 348 N.E.2d 571 (N.Y. 1976).

235. *Id.* at 577 (quoting *Palmer v. Massey-Ferguson*, 476 P.2d at 719). It should be noted, but only in passing, that *Micallef* was brought under theories of negligence and implied warranty, not strict liability (which had only been recognized as a theory in New York since the case had been brought). Since the reasonableness of product design is implicated under both negligence and "strict" product liability, the choice of theory makes

Seen through the unerring lens of hindsight, statements such as the above amount to an acknowledgement of the regulatory effect of imposing liability for obvious and open design choices. Indeed, the *Micallef* court noted that the earlier rule denying recovery was "founded on the notion that it should be the task of the Legislature, not the courts, to compel manufacturers to install possible safety devices."<sup>236</sup>

During the 1970s, the abandonment of the patent danger rule, along with a more general, expanding recognition that liability could be properly imposed for conscious design decisions, unleashed a welter of complexities, which courts have never since managed to rein in. Although the consumer expectation analysis was far from tidy, it at least limited the class of claims to those involving an element of tacit misrepresentation.<sup>237</sup> Without that test, design defect cases—and similarly, cases involving failure to warn—were dropped back into the vast, unpredictable sea of negligence.

The best known attempt to give the expanding concept of defect some content is the risk-utility test, first proposed by Professor Wade. It has often been stated that the risk-utility test is one of negligence. While it is true that the factors involved in making the determination of defectiveness under this test have a negligence core, an attempt was made to go beyond the central question of reasonableness on the defendant's part and to look at a number of important questions concerning the product, the litigants, and the market.<sup>238</sup>

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little difference here; once gone in this negligence case, the patent danger rule did not resurface in New York.

236. *Micallef*, 348 N.E.2d at 576.

237. Writers of the leading torts treatise probably overstate the point somewhat, stating that the patent danger rule "is a vestigial carryover from pre-*MacPherson* days when deceit was needed for recovery." 5 HARPER, JAMES & GRAY, *THE LAW OF TORTS* § 28.5, at 369 (2d ed. 1986).

238. The factors are: (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole; (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury; (3) The availability of a substitute product which would meet the same need and not be as unsafe; (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility; (5) The user's ability to avoid danger by the exercise of care in the use of the product; (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 837-38 (1973).

At first blush, it may appear odd that such a balanced approach, relying as it does on a list of arguably reasonable factors, should have engendered such resentment from product sellers and their insurers. At least four reasons have nurtured this publicly expressed dissatisfaction.

First, one should keep in mind that the imposition of *any* liability for conscious design decisions represented a formidable expansion. With the risk-utility test in place, consumers injured by products lacking safety guards, by uncrashworthy cars, and by virtually any product that *could* somehow have been made safer began to queue up at the courthouse; many recovered.<sup>239</sup>

Second, given the state-by-state approach to product liability adjudication, the regulatory aspect of judicial results sometimes placed manufacturers in a quandary. A decision in state X might lead a manufacturer to design a machine with stabilizing extensions, for example, while a decision in state Y might find the manufacturer liable for doing just that. Thus, the manufacturer would have to choose the design believed likeliest to impose the lowest overall costs (necessarily a guess), or come up with some third design, or cease production altogether. The spectre of inconsistency is simply not present with manufacturing defects since by hypothesis the product is not designed to be defective in that way.

Third, courts sometimes went beyond the establishment of a risk-utility test and tinkered with procedural rules so as to benefit plaintiffs. One important example is the seminal case of *Barker v. Lull Engineering Co.*,<sup>240</sup> in which the California Supreme Court stated that, under the risk-utility test, "once the plaintiff makes a *prima facie* showing that the injury was proximately caused by the product's design, the burden should appropriately shift to the defendant to prove . . . that the product is not defective."<sup>241</sup>

Finally, and perhaps most troubling to manufacturers, courts have at times toyed with the notion that a product's defectiveness should be judged without regard as to whether a safer alternative was possible. In *O'Brien v. Muskin Corp.*, the New Jersey Supreme Court dismayed manufacturers by holding that "[a]lthough state of the art evidence may be dispositive on the facts of a particular case, it does not consti-

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239. See, e.g., *Vrooman v. Beech Aircraft Corp.*, 183 F.2d 479 (10th Cir. 1950); *Pike v. Frank G. Hough Co.*, 467 P.2d 229 (Cal. 1970); *Larsen v. General Motors Corp.*, 391 F.2d 495 (8th Cir. 1968).

240. 573 P.2d 443 (Cal. 1978).

241. *Id.* at 455.

tute an absolute defense. . . . [T]he burden is on the defendant to prove that compliance with state of the art . . . justifies placing a product on the market."<sup>242</sup>

If compliance with the state of the art at the time of manufacture will not suffice to relieve a manufacturer of liability, then even completely reasonable design decisions—indeed, even decisions made without realistic available alternatives—could result in liability. Thus, any consumer injured by a product that, given *present* knowledge or technology, could have been safer, would be able to recover for injuries caused by the product's "defect." In practice, however, the state of the art defense has usually received judicial recognition. Further, as New Jersey's experience demonstrates, the legislature has been willing to step in where courts have been slow to credit the defense.<sup>243</sup>

### ***B. Domestic Reform of the Law of Defective Products***

It was into this unmapable legal landscape that the reformers arrived. It would be a mistake to assume that all who wish to limit the class of, or the amount paid to, product-accident victims have similar goals in mind. In the analysis that follows, I discuss what might be termed the mainstream reform movement. It is led by those who are concerned about the cost and availability of product liability insurance and the effect of product liability litigation on competitiveness, but who are also concerned that plaintiffs with legitimate claims should be reasonably compensated for their injuries.<sup>244</sup>

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242. 463 A.2d 298, 305 (N.J. 1983).

243. In *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539 (N.J. 1982), the court plainly refused to recognize the defense in the asbestos case, but the damping legislative response was swift. See N.J. STAT. ANN. § 2A:58C-3 (West 1987):

a. In any product liability action against a manufacturer or seller for harm allegedly caused by a product that was designed in a defective manner, the manufacturer or seller shall not be liable if: (1) At the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product . . . .

b. The provisions of paragraph (1) of subsection a. . . . shall not apply if the court, on the basis of clear and convincing evidence, makes all of the following determinations: (1) The product is egregiously unsafe or ultra-hazardous; (2) The ordinary user or consumer of the product cannot reasonably be expected to have knowledge of the product's risks, or the product poses a risk of serious injury to persons other than the user or consumer; and (3) The product has little or no usefulness.

244. The extreme pro-Defendant position expressed by the unreconstructed contractarians represents a tiny fraction of the literature and is not the subject of this Article. The most notorious among these corporate apologists is probably Peter Huber, who has expressed his position eloquently in *PETER HUBER, LIABILITY: THE LEGAL REVOLUTION*

The Model Uniform Product Liability Act is part of the reform movement and defines a broad legislative response to the confusion into which product liability law had descended by the early 1980s.<sup>245</sup> Many of the provisions of MUPLA have been enacted into law in several states. For these reasons, MUPLA is used as a model for analysis here.

MUPLA begins with a section entitled "Findings" which speaks to the commercial dislocations caused by "sharply rising product liability insurance premiums."<sup>246</sup> The drafters worried about higher prices for products, disincentives for innovations and for risky products, the hazards of uninsured producers, and hastily enacted, ill-considered legislation that might unfairly affect claimants' rights. This section also address the problems created by the state-to-state uncertainty of litigation outcomes, which adversely affect both the insurance market and the judicial system.

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AND ITS CONSEQUENCES (1988). He makes plain his preference for the "rugged world" in which "contract principles . . . could operate very harshly." *Id.* at 24. He therefore approves of a no-liability result in a 1937 disaster involving Massengill, which had manufactured a "miracle drug" that was never tested on animals, and then "promptly killed 100 people." *Id.* Huber states: "If users of the drug had wanted a guarantee of its safety and effectiveness, they should have demanded one before buying. No such guarantee had been provided." *Id.* In these good old days, "a deal was a deal." *Id.* Sometimes, legal refutation is no substitute for plain moral revulsion. If any reason beyond one's sense of outrage is needed, consider that the purchasing public should be entitled to rely on a manufacturer's taking of reasonable precautions for its safety before rushing a drug to market. Disallowing recovery in such a case devalues the consumers' reasonable expectations of safety, and could reward not only corporate negligence, but intentional injury-causing acts as well.

245. Examples are set forth *supra*, note 2.

246. MUPLA was published by the Department of Commerce after an extensive inter-agency Task Force study concerning products liability. The Task Force "found that uncertainties in the tort litigation system were a principal cause of the product liability problem." MUPLA, *supra* note 1, Background of the Act, Appendix A, commentary at 281. The Task Force report was presented to representatives from the Office of Management and Budget and the Domestic Policy Staff of the White House who requested that the Department of Commerce prepare an options paper on what action the Federal Government should take to address the product liability problem. The options paper included a proposal for a uniform product liability law. After favorable responses to this recommendation, the Department of Commerce published the "Draft Uniform Product Liability Law" in the Federal Register for public comment. The Department of Commerce received approximately 1500 pages of commentary regarding the draft. In addition, the Department of Commerce brought the draft to the attention of consumer groups, and representatives of product seller and insurer groups. The draft was also reviewed before the Subcommittee on Oversight and Minority Enterprises of the House Committee on Small Business and before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce. MUPLA was published on January 8, 1982, and "has benefited substantially from its review by, and input from, the various groups affected by the product liability problem." *Id.* at 282.

Given these concerns, one might have expected a comprehensive overhaul of product liability law or at least retrenchment. MUPLA is instead remarkably measured, offering much in the way of procedural reform but little truly substantive change.<sup>247</sup> This result is neither surprising nor wrong. The current section attempts a conceptual summary of MUPLA, grouping together provisions that speak to the two overarching issues: the substantive rights of litigants and the conduct of the litigation.<sup>248</sup>

### 1. MUPLA's Effect on the Substantive Law of Product Defects

One is first struck by the small number of provisions devoted to substantive reform. Only five of twenty-three sections deal with the basic responsibility of product sellers, while an additional two sections concern reducing liability based on the conduct of the plaintiff or of third parties. In contrast, nine sections can be comfortably placed in the "conduct of litigation" category. More significantly, the substantive responsibility sections, with some exceptions, are much more open-ended than the other provisions.

#### a. Defining Defect and Fixing the Standard of Liability

The centerpiece of MUPLA, which is intended to preempt virtually all existing product liability law,<sup>249</sup> is section 104 which provides "Basic Standards of Responsibility for Manufacturers."<sup>250</sup> However,

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247. Both the proposed Restatement (Third) of Torts and an ALI report (1 AM. L. INST., Reporters' Study on Enterprise Liability for Personal Injury 3-52 (1991), Introductory Chapters reprinted in 30 SAN DIEGO L. REV. 371 (1993)), came to the same result, except that both made the mistake of doing away with the consumer expectation test in favor of the risk-utility calculus. See *infra* subpart IV.B.1(a) (on MUPLA) and ALI Reporters' Study, *supra* at 414 ("There should be no separate 'consumer expectations' test for design defect . . . .")

248. Of course, the dichotomy can be criticized as forced, even false. After all, the procedural mechanisms established by any piece of legislation do have an effect, sometimes a dispositive one, on a litigant's chances of success. Conversely, certain procedural changes might be rendered irrelevant by a preemptive change in the substantive law. For the reasons I develop throughout this Article, however, I am convinced that the distinction is worth making, because it can enable comprehensive understanding of the value of particular attempts at reform.

249. MUPLA, *supra* note 1, § 103(A). This preemption does not apply to claims for commercial loss, which are expressly *not* covered by the Act. See *id.* § 102(F) (defining "harm" as excluding "direct or consequential economic loss"). Such damages can still be recovered "under the 'Uniform Commercial Code' or similar laws." *Id.* § 103(A).

250. "Manufacturer" is broadly defined as "a product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer. It includes a product seller . . . not other-

this section undoubtedly disappointed those expecting to find a change in the law governing liability for defect.

The section begins by sorting out the various types of product defect cases long recognized by courts. It announces that separate subsections will deal, respectively, with products "unreasonably unsafe in construction, in design, and in inadequacy of warning."<sup>251</sup> As to all three, liability is—at least by definition—strict under the provision: "A product manufacturer is subject to liability to a claimant who proves . . . that . . . the harm was proximately caused because the product was defective."<sup>252</sup> Absent from that definition of "defect" is any mention of "fault" or of "reasonableness." But, as has developed in domestic law, the inquiry into defect itself typically comprehends a reasonableness analysis. The qualifier "typically" in the preceding sentence was necessary to exclude manufacturing or construction defects, which the drafters believed should continue to create strict liability. As to these episodic, unintended defects, MUPLA simply requires that the "product deviated in some material way from the manufacturer's design specifications or performance standards, or from otherwise identical units of the same product line."<sup>253</sup>

Manufacturing defects aside, MUPLA contemplates a full-dress analysis of the "reasonableness" of the product in design defect cases. A product is "unreasonably unsafe in design" if it is found that "at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms outweighed the burden on the manufacturer to design a product that would have prevented those harms, and the adverse effect that alternative design would have on the usefulness of the product."<sup>254</sup> Article 104(B) then provides examples of evidence that is "especially probative" in evaluating a product allegedly defective in design; however,

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wise a manufacturer that holds itself out as a manufacturer." *Id.* § 102 (B). This last sentence is properly sensitive to the representational dimension of a product liability claim.

251. I set aside the separate category of express warranty, used throughout MUPLA. MUPLA essentially grants a product liability claimant an additional path to relief if she can demonstrate that an express warranty was breached. Since these express warranties cannot operate through their limitations as disclaimers, they cannot grant less relief than would otherwise be available. These warranties, while an effective means of recovery in some cases, stand apart from the great bulk of product defect law for personal injury; they do not raise any special difficulties that concern us here. Therefore, I do not dwell on them further in this Article.

252. *Id.* § 104.

253. *Id.* § 104(A).

254. *Id.* § 104(B)(1).

the list is neither exhaustive nor too specific.<sup>255</sup> In short, the "defect" label goes on only after the "reasonableness" analysis goes in.

MUPLA's treatment of the warning issue parallels negligence principles and thereby represents no substantial change from the case law.<sup>256</sup> A product is deemed "unreasonably unsafe" by virtue of inadequacy of warning if "the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms rendered the . . . instructions inadequate and that the manufacturer *should* and *could* have provided . . . instructions or warnings."<sup>257</sup> With its overtly moral language, the adequacy of warning provision focuses judicial attention squarely on the conduct of the manufacturer: Under the circumstances, *should* the manufacturer have provided the contested warnings? This is a far cry from strict liability.

Underscoring that point are examples of especially probative evidence of a warning's adequacy which speak to the conduct of the manufacturer, even more so than is the case with design defect: Was the manufacturer able to know of the product's danger or to anticipate that the likely user would be aware of any danger? How feasible and practical would it have been to provide warnings? How clear and conspicuous were any warnings that were provided?<sup>258</sup>

MUPLA's provisions reflect the fact that a more developed body of doctrine has sprung up around the duty to warn than in the design defect area. Its subsections, however, adopt the typical Restatement approach; in the closer cases the drafters chose what they considered to be the best among the available alternatives. Thus, MUPLA follows the uncontroversial view that a "manufacturer shall not be liable for its failure to warn . . . about dangers that are obvious,"<sup>259</sup> but takes a bolder stand on the issue of whether, and under what circumstances, conveying a warning to an intermediary relieves the manufacturer of liability to the ultimate user. In sum, MUPLA generally applies the learned intermediary rule,<sup>260</sup> relieving manufacturers of liability

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255. The trier of fact is urged to give attention to: "warnings and instructions"; the feasibility of a product that would have prevented the harm while remaining useful; "the effect of any proposed alternative design on the usefulness of the product"; the cost of the chosen design, as opposed to available alternatives; and other harms "that might have resulted if the product had been . . . alternatively designed." *Id.* § 104(B)(2)(a)-(c).

256. See Hager, *supra* note 13, at n.31 (citing cases) and accompanying text.

257. MUPLA, *supra* note 1, § 104(C)(1) (emphasis added).

258. *Id.* § 104(C)(2)(a)-(d). Subsection (e) calls the "adequacy" of the warnings important, but this provision simply reformulates the basis of liability. *Id.* § 104(C)(2)(e).

259. *Id.* § 104(C)(4).

260. *Id.* § 104(C)(5). The Act provides that a manufacturer may be relieved of the duty to warn the user if it provides warnings "to a person who may be reasonably expected to



where the warning is more sensibly provided to the person best positioned to convey it to the class of ultimate users. MUPLA also adopted a more specific rule for the workplace: When there is "no practical and feasible means" of informing the employee of the danger, warnings may stop with the employer. Finally, MUPLA attempts to impose order on the currently cluttered question of postmanufacture duty to warn. Rejecting the blanket no-liability position, MUPLA imposes a duty to warn where "a reasonably prudent manufacturer should have learned about the danger associated with a product after it was manufactured."<sup>261</sup> Subsequently, the manufacturer must act reasonably by attempting "to inform product users" or others in a position to prevent harm.

This analysis of the salient provisions of section 104 demonstrates that MUPLA's drafters did not seek an overhaul of the jurisprudence of defect—a body of law reached only after great difficulty by the courts. Nonetheless, the law of defect was swept clean in several respects.

First, the drafters openly cast their lot with a negligence-based standard of liability in all but manufacturing defect cases. The reasons for doing so were two-fold: First, as a practical matter, the availability of closely related theories of negligence and strict liability at trial had caused courts to "drift . . . toward verbal formulas that attempt to distinguish" between the two.<sup>262</sup> Similarly, "[n]o court, in spite of some loose language . . . has imposed true strict . . . liability."<sup>263</sup> Courts and the drafters alike recognized the frightening possibility of limitless liability inherent in true strict liability: "[I]t is almost always possible to design a product more safely."<sup>264</sup>

Second, the drafters flatly abandoned the consumer expectation test. They stated that this radical step was taken because, in most cases, the consumer would not have any idea of what to expect. Even where some expectation could be found, the drafters found the test too subjective: "Each trier of fact is likely to have a different understanding of abstract consumer expectations."<sup>265</sup> Between the lines,

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assure that action is taken to avoid the harm, or that the risk of the harm is explained to the actual product user."

261. *Id.* § 104(C)(6).

262. *Id.* § 104, app. A, commentary at 297. Extending the metaphor, the drafters noted that the courts "have plunged into a foggy area that is neither true strict liability nor negligence." *Id.* at 298.

263. *Id.* at 299.

264. *Id.*

265. *Id.* at 301.

one can discern an additional source of disquiet concerning the older test: it is embodied in section 402A of the Restatement, which, the drafters sought to jettison as unresponsive to defects other than those of manufacture.<sup>266</sup>

MUPLA's radical departure from the well-worn consumer expectation test directly conflicts with the approach taken by the product liability directive. As previously stated, the Directive makes plain its preference for the consumer expectation test in defining defect.<sup>267</sup> Indeed, the interesting question under the Directive has been whether its definition of defect leaves room for a risk-utility analysis.<sup>268</sup>

It is submitted that the drafters of MUPLA went wrong in doing away with the consumer expectation test.<sup>269</sup> As shown above, their reasons for doing so centered around the uncertainty of outcome that the test can yield. But that uncertainty is likely to be a problem only in those difficult cases where the consumer's expectation is hard to gauge. In many cases, jurors can, without reservation, assess what a reasonable consumer would have expected. Even where that is difficult, the inquiry should focus on the safety that a reasonable consumer has the right to expect, rather than on a risk-utility analysis a manufacturer makes, which allows the consumer's safety to be too easily subverted.

If there is a manufacturing defect, for example, the injured product user recovers precisely *because* the product was more dangerous than expected. As pointed out in the earlier discussion of the history of product liability,<sup>270</sup> the same can be said of many latent defects, even where the problem is of design. These simple findings would conserve scarce judicial resources. It makes little sense for attorneys

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266. "Much of the controversy appears to have sprung from the fact that the authors of Section 402A of the 'Restatement (Second) of Torts' were focusing on problems relating to product mismanufacture . . . and not on problems relating to defective design or the duty to warn." *Id.* at 297. This statement overlooks at least comment j and comment k to that famous text, which expressly address the problems of warnings.

267. See discussion *supra* subpart III.B.2.

268. Professor Shapo seems to believe that no room remains for risk-utility principles under this approach: "Conspicuous by their absence are notions of cost-benefit and risk-utility analysis . . ." Shapo, *supra* note 107, at 292.

269. At the same time, I recognize that the trend is overwhelmingly in the direction of the risk-utility test. One fairly recent attempt to work within the strictures of that test is found in W. Kip Viscusi, *Wading Through the Muddle of Risk-Utility Analysis*, 39 AM. U. L. REV. 573 (1990), in which the author seeks to make the test more useful, even more mechanical, by reorganizing the factors and by offering some supplemental considerations of his own.

270. See *supra* subpart IV.A.

to put on a complicated, and usually expensive, risk-utility play when a much simpler standard is at hand.

Further, the consumer expectation test, faithfully applied, better serves the requirements of justice by including the consumer—either actually or by a “proxy of his peers”—in decisions crucially affecting his physical and emotional health. Such an approach also values the consumer’s decision to purchase products he knows pose a danger by disallowing recovery in those cases, assuming that the choice is not coerced.

### *b. Liability of Nonmanufacturing Sellers*

In something of a sidebar to the development of the central tenets of product liability law, the responsibility of nonmanufacturing sellers of defective products has its own peculiar history. While suits against these sellers were less likely to be frustrated by the privity rule, the continued insistence on negligence meant that, until recently, tort claims against nonmanufacturers were unlikely to succeed. The plaintiff had to prove some act of negligence on the part of a defendant who was usually a mere conduit between manufacturer and purchaser. Of course, the increased willingness of courts to allow the skirting of the negligence requirement (and thus the limitations imposed by tort) by recognizing claims grounded in implied warranty meant that immediate product sellers began to be haled into court, and were often found liable.<sup>271</sup> Thus an anomalous result was achieved: Absent negligence, the immediate seller—typically the retailer, in consumer goods cases—was more likely to be liable than was the party responsible for the defect. Since warranty liability was strict, the retailer’s presumed inability to inspect the product for defects did not operate as a defense.

Inasmuch as warranty liability derives in part from the string of contracts involving the sale of a given good,<sup>272</sup> the retailer could in turn sue the next party up the chain of distribution who could then seek indemnification against *its* seller, and so on, until the defect-creating manufacturer was ultimately reached. This clumsy approach has

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271. *Cushing v. Rodman*, 82 F.2d 864 (D.C. Cir. 1936); *McCabe v. Liggett Drug Co.*, 112 N.E.2d 254 (Mass. 1953); *see generally* U.C.C. §§ 2-314, 2-316 (1995).

272. Because courts have moved fluidly between tort and contract principles in interpreting rights under warranties, the phrase “in part” is a necessary qualifier. *See generally* W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 95A (5th ed. 1984).

been justly criticized,<sup>273</sup> and not surprisingly, it became unnecessary within a short time. Courts began to allow suits in warranty against remote sellers<sup>274</sup> and, by discarding the negligence requirement in tort, came to permit liability suits even against those middle sellers who did not have a reasonable opportunity to inspect.<sup>275</sup>

However, this move did not go uncriticized,<sup>276</sup> nor was it universally accepted by the courts.<sup>277</sup> After all, many of the principal justifications advanced in support of abrogating the negligence requirement against manufacturers of defective goods do not apply to others in the chain of distribution. Problems of proving negligence, for example, are usually irrelevant to the downstream seller who did not create the defect in the first place. Similarly, the goal of providing incentives to the manufacturer to produce safe products is facially inapplicable to nonproducers. Finally, and perhaps most troubling, the argument based on notions of corrective justice seems weakened, if not defeated, as to nonmanufacturers. To state the issue simply: How can justice require the middle seller to pay the injured consumer for an injury caused by someone else?

These problems notwithstanding, most courts have allowed injured product users to pursue claims against nonmanufacturing sellers. The reasons for doing so were again best captured by Justice Traynor: the manufacturer may not be amenable to suit, leaving the plaintiff remediless unless others in the chain of product distribution are liable; and the middlemen may be in a position to exert pressure on the manufacturer to strive toward greater product safety.<sup>278</sup>

273. *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436, 441-42 (Cal. 1944) (Traynor, J., concurring).

274. *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. Sup. Ct. 1960).

275. This approach is consistent with that taken by the RESTATEMENT (SECOND) OF TORTS § 402A (1966) (imposing a duty of strict liability duties on all commercial sellers). See *Vandermark v. Ford Motor Co.*, 391 P.2d 168 (Cal. 1964); *Visnoski v. J.C. Penney Co.*, 477 So. 2d 29 (Fla. Dist. Ct. App. 1985).

276. *Culhane*, *supra* note 182, at 293-95; see also John B. Waite, *Retail Responsibility and Judicial Law Making*, 34 MICH. L. REV. 494, 519 (1936) ("[i]f there be a reason, a public gain in the transfer of the loss from the customer to the retailer, the writer is not aware of it.").

277. See, e.g., *Sam Shainberg Co. v. Barlow*, 258 So. 2d 242 (Miss. 1972) (refusing to find liable either the retailer or the wholesaler of a pair of shoes which contained a latent defect but had never been removed from their original package until they were moved to an in-store rack).

278. *Vandermark v. Ford Motor Co.*, 391 P.2d 168, 171 (Cal. 1964). This last point applies only to situations involving manufacturers and middlemen who deal with each other on a regular basis. The point may not be valid where manufacturers who end up paying tort judgments are not actually turning out unsafe products and where nonmanufacturing

Perhaps because courts and commentators were convinced that compensating the injured was the true reason for extending liability to nonmanufacturers, the Act and a number of state statutes have neatly responded to the problem without dragging these sellers into the litigation unnecessarily.

Under section 105 of the Act, the nonmanufacturing seller is usually liable only if negligent in its own right; a claimant can recover by proving that her "harm was proximately caused by . . . [the] product seller's failure to use reasonable care with respect to the product."<sup>279</sup> The statute then sets forth what amounts to a corollary rule under which liability is improper absent "a reasonable opportunity to inspect the product" in a way that would (or should) have revealed the defect.

Nonnegligent middle sellers are therefore typically exempt from liability. But concern for the victim trumps the desire to completely absolve nonmanufacturers; section 105 subjects these product sellers to liability where, either due to lack of jurisdiction or insolvency, the manufacturer fails to provide relief to the plaintiff.<sup>280</sup> The drafters also provided a catch-all protection which applies where the court finds it "highly probable that the claimant would be unable to enforce a judgment against the product manufacturer."<sup>281</sup>

This compromise seems a more satisfactory resolution than that achieved by the Directive—which allows the nonmanufacturing supplier to escape liability simply by "identifying" the manufacturer. The Directive makes no provision for those cases in which the manufacturer is identifiable, but for one reason or another cannot be reached.

The Act admirably cuts away much of the confusion that has surrounded product liability by offering one streamlined statute to supplant the warring tort theories of implied warranty, negligence, and strict liability in tort. Dispensing with implied warranty, however, removes the UCC's clear imposition of liability against middle sellers. This result can be countenanced if the plaintiff is to recover in any case, but becomes indefensible under the Directive's approach, where a product-injured party can find himself without redress.

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sellers lack sufficient knowledge or market power to affect the manufacturer's decision. See Culhane, *supra* note 182, at 293-94.

279. MUPLA, *supra* note 1, § 105(A). Section 105 further illuminates the conduct required for liability: "[T]he trier of fact shall consider the effect of such product seller's own conduct with respect to the design, construction, inspection, or condition of the product, and any failure of such product seller to transmit adequate warnings or instructions about the dangers and proper use of the product." *Id.*

280. *Id.* § 105(C)(1)-(2).

281. *Id.* § 105(C)(3).

It is a close question whether corrective justice requires nonmanufacturing, nonnegligent sellers to compensate injured product users (or bystanders) where the producer is absent. Some have argued that, if the nonmanufacturer is to be released from liability on the premise that it neither caused the defect nor was negligent in any other material respect, then there is no reason for holding it liable just because the manufacturer turns out to be unavailable. This policy is followed by at least a few states which refuse to hold the nonnegligent middle seller liable even where the manufacturer cannot be reached.<sup>282</sup>

On the other hand, the middle sellers *are* involved in the chain of distribution, *may* be in a position to influence the manufacturer, and *usually* are better able to absorb the cost than the product's injured user. Presumably for these reasons, both the Act and a great majority of state statutes expressly permit suit against nonmanufacturers where necessary for recovery.<sup>283</sup> Moreover, in a sense, the intermediate distributors of the product contributed to causing the injury by allowing the defective product to come into the injured party's possession. Accordingly, it makes sense that the middle sellers be left "standing by" to compensate as needed, but that they be otherwise freed from liability. The Act agrees, criticizing the approach of the minority of states: "[T]he [pure nonliability] approach can leave a person injured by a defective product . . . without compensation. [I]n these situations, the party who actually sold . . . the defective product should bear the loss."<sup>284</sup>

Finally, it is worth reiterating that the middle seller's liability has long (and properly) been recognized as stemming from the reliance that buyers place upon their immediate sellers. This point is in some sense a corollary to the perception that nonmanufacturing sellers have the ability to structure their relationships with the manufacturer—at least by contractual indemnification provisions—so as to place themselves in a better position to ensure the safety of a product than at least the consumer.

### c. *Special Liability Rules for "Problem" Products*

This section groups for discussion sections 106 through 108 of the Act. None of these sections is invoked in the run-of-the-mill product liability case. For example, if the product contains a defect of manu-

282. See, e.g., GA. CODE ANN. §§ 105-106.1 (Harrison 1991); NEB. REV. STAT. §§ 25-21, 181 (1989); S.D. CODIFIED LAWS ANN. § 20-9-9 (1995).

283. Many of these statutes are collected in Culhane, *supra* note 182, at 287-88 n.3.

284. MUPLA, *supra* note 1, app. A, § 105 cmt.

facture, or if alternative designs were available but deliberately disregarded, the tests for defect found within section 104 would suffice. Sections 106-108 only apply where the manufacturer is arguing that the product could not or should not have been made safer, either by design or by accompanying warning.

Section 106 echoes comment k to Restatement (Torts) section 402A and imposes negligence-based liability on sellers of "unavoidably dangerous" products. Such products are those that, in light of available knowledge at the time of manufacture, are incapable of being made safe without impairing their usefulness.<sup>285</sup> Manufacturing defects and express warranties aside,<sup>286</sup> a product seller will not be liable for harm caused by these products unless the seller knew or should have known of the unavoidably dangerous aspect of the product—and therefore either "acted unreasonably in selling the product at all" or "failed to meet a duty to instruct or warn under subsection 104(C), or to transmit warnings or instructions under subsection 105(A)."<sup>287</sup>

These two possible grounds for liability deserve separate attention. The first liability basis, referring to those unavoidably unsafe products that should not be marketed at all, constitutes a dramatic departure from comment k, which limited its focus to products that were both unambiguously useful (mostly drugs<sup>288</sup>) and yet hazardous in some respect. The Act's reference to products that should not have been sold "at all" is given context by the example provided in the analysis accompanying section 106. Referring to the "unusual" situation calling for disposition under this rule, the drafters cited the example of "a product seller who markets a toy that is highly dangerous to

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285. *Id.* § 106(A).

286. These situations are dealt with by MUPLA § 106(B)(2) (manufacturing defects) and 106(B)(4) (express warranties). As stated earlier, the former are subject to a strict liability standard throughout MUPLA, while express warranties announce their own bases of liability.

287. MUPLA, *supra* note 1, § 106(B)(1), (3).

288. There has been some debate about whether comment k should be read as applying only to drugs. All of the examples given in the comment refer to drugs, so the tendency has been to consider only the drugs that are covered by its terms. But that conclusion is not dispositive. The comment refers to drugs as an "especially common" instance of unavoidably unsafe products. Thus, it has been argued that the class of such products should neither be germinated nor limited by drugs. See Theresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357, 1363 n.33 (1994) (collecting cases that refuse "to adopt bright-line rules that would treat all prescription drugs and devices as deserving of special . . . rules").

children." Note that the seller is held liable in this case even if the product is accompanied by proper warnings.

The second liability basis, failure to provide adequate warnings for products that present an unavoidable risk, is a close cousin of comment k: both impose liability for selling unavoidably dangerous products without an accompanying warning and both focus on drugs and similar products, such as blood. The Act and the Restatement thus share the perception that the risk inherent in virtually all drugs, or bodily products, is outweighed by their curative effect.

That said, one might question whether a drug seller could be liable for failing to warn users that a drug's dangers were yet unknown. This possibility surfaces in cases where experimental drugs are rushed to market without much testing, because even quite serious side effects are preferable to the illness that the drug was designed to combat. Drugs treating the HIV virus, which causes AIDS, are the most dramatic contemporary example.

In this circumstance, should a duty to warn attach? The Act seems to answer no. Under section 106(B)(3), liability will be imposed only if the seller "knew or had reason to know of the [unavoidably dangerous] aspect and failed . . . [to] warn." Unless the user of an experimental drug could establish that the seller had reason to know of a particular danger posed by the drug, liability would seem precluded.<sup>289</sup>

One additional point must be made concerning section 106. It will be recalled that section 104, establishing the basic liability rules for producers of defective products, treats both the seller's knowledge of dangers associated with the product, and its ability to design a suitable alternative, as factors that are "especially probative" in determining whether a product is defective. Section 106 thus creates an important qualifier to section 104's general language: Whenever a product is "unavoidably unsafe," liability will not attach unless the seller had reason to know of the defect.

Section 107 of the Act picks up the thread from section 106, addressing related issues of liability for risks that are difficult, if not impossible, to eliminate. The section is somewhat more complicated however, containing rules of evidence and substantive liability principles, and dealing with a wider spectrum of conduct and products than does section 106.

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289. For criticism of this position, see *infra* subpart V.D.



Subsection (A) of section 107 deals with the thorny evidentiary issue of the relevance of changes in a product, or in the surrounding environment, after a product's manufacture.<sup>290</sup> Unequivocally resolving a long-standing controversy, the Act simply states that postmanufacture changes in a product's design, in a product's accompanying warnings, or in the custom or technology in the field are inadmissible "for the purpose of proving that the product was defective," as the prejudicial effect of such remediation evidence outweighs its probative value.<sup>291</sup> The sound analysis accompanying the section indicates the drafters' awareness of the strength of the competing positions on this issue.<sup>292</sup>

As to the "custom" in the relevant industry<sup>293</sup> at the time of manufacture, and as to compliance (or noncompliance) with "a non-governmental safety or performance standard," the Act takes a middle-of-the-road approach. These elements are evidence for the trier of fact to weigh in ascertaining whether the product was defective or accompanied by insufficient warnings. The Act properly recognizes that relevant customary standards of manufacture, as well as private performance and safety standards, are usually present for sound reasons and that the trier of fact should at least be permitted to consider the manufacturer's adherence to these standards in resolving the liability issue. At the same time, the drafters acknowledge that custom may lag behind what a reasonable manufacturer would do, and that private

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290. I disagree with the Act's decision to freeze liability at the time of manufacture. It may be that the manufacturer retains the product for some time after it is manufactured; if so, the manufacturer should be responsible for making necessary changes in light of new information before selling the product. In short, control of the product, which does not end until sale, should be the touchstone of liability.

291. MUPLA, *supra* note 1, § 107(A).

292. See *id.* § 107 (accompanying analysis). The drafters recognize that some courts have criticized the argument that allowing evidence of subsequent changes in the product or in the surrounding technology would make manufacturers less likely to undertake product changes. This criticism is based on the notion that, at least in some cases, the manufacturer will be better off making the changes so as to avoid paying an even greater number of product-injured plaintiffs in the future. The drafters emphasize instead the highly prejudicial nature of such remediate evidence. Although subsequent improvements to a product may seem irrelevant to the issue of whether a product was defective at the time of its manufacture, the evidence goes to whether a feasible alternative was available—implementation of prompt remediation suggests that it was. So the argument against allowing such evidence is not strictly logical, but is based on the weight a jury might afford the evidence.

293. The Act defines "custom" as follows: "[T]he practice followed by an ordinary product seller in the product seller's industry or business." MUPLA, *supra* note 1, § 107(B).

safety standards may exhibit "variance in [their] nature and quality."<sup>294</sup>

The treatment given to custom by section 107 unmasks another virtue of the Act. Simply put, the Act separates different terms frequently lumped together as "state of the art." According to the drafters, the controversy over whether to recognize compliance with the state of the art as a defense can be simplified, if not resolved, by doing away with the term entirely. State of the art has been used in inconsistent ways, with courts running the definitional gamut from "custom" to the "aggregate of product-related knowledge existing at any given point in time."<sup>295</sup>

In separating these obviously disparate notions, the Act treats custom differently from "practical technological feasibility." While adherence to or departure from custom is simply evidence relating to the issue of defect, practical technological feasibility involves a shift of the burden of proof. If the product seller can prove "that it was not within practical technological feasibility to make the product safer . . . so as to have prevented claimant's harm,"<sup>296</sup> a presumption of no liability arises.

Consistent with the logic of the Act, manufacturing defects and express warranties can defeat the presumption. Moreover, the presumption does not relieve a manufacturer of any postsale duty to warn that might be incurred under section 104(C)(6). Otherwise, the presumption renders the manufacturer liable only if—with knowledge or reason to know of the danger—it acted unreasonably in selling the product at all.<sup>297</sup> The analysis provides two examples of what might be considered unreasonable conduct in this setting: one is the trusty "child's toy," while the other is a "home heating unit with a radium core." Although the second is a bit puzzling,<sup>298</sup> the first is consistent both with the recognition in section 106 that a manufacturer might be liable for selling a product with an unavoidably unsafe feature, and

294. *Id.* app. A, § 107 (accompanying analysis).

295. Note, *Product Liability Reform Proposals: The State of the Art Defense*, 43 ALB. L. REV. 941, 945-46 (1979).

296. MUPLA, *supra* note 1, § 107(D).

297. *Id.* § 107(E)(1).

298. There are alternatives to home heating units with radium cores, or else we would all be dead. Perhaps the example could be salvaged by arguing that a product using a different element to supply the heat would be a different product altogether, but little seems to be gained in making the point. A better example might have been asbestos, assuming there is no alternative fire-retardant. Should liability be imposed in that case? See Part I, *supra*.

with a strain of the case law that has been willing to impose liability on those who sell even the most technologically advanced product, if that product (on a risk-utility analysis) should not be sold at all.<sup>299</sup>

Section 108 brings to rest the issue of compliance with standards by addressing the effect of public regulatory standards and mandatory government specifications. Taking the simpler issue first, the Act speaks plainly on the subject of compliance with mandatory design specifications issued by the government: If compliance nonetheless results in an injury-causing defective product, "the government, not the product seller, is the appropriate defendant."<sup>300</sup> On the other hand, if the specifications are not met, and the claimant's injury is the proximate result of that noncompliance, "the product shall be deemed defective." Although the drafters did not so state, the apparent reason for these conclusive presumptions is that product sellers, shielded by a no-liability rule through compliance, should be subject to a strict liability rule where they fail to exercise the straightforward means of escaping liability with which they have been provided.

A more typical case that would arise under section 108 involves the product subject to legislative or administrative regulation before reaching the market. In these cases, subsections (A) and (B) of section 108 adopt a mirrored approach: If standards are complied with, the product is presumptively nondefective; if not, the product is presumptively defective.

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299. The case that has been most often cited on this point is *Beshada v. Johns-Manville Prods. Co.*, 447 A.2d 539 (N.J. 1982) (state of the art defense not permitted in asbestos case). Similarly, in *O'Brien v. Muskin Corp.*, 463 A.2d 298 (N.J. 1983), the New Jersey Supreme Court held it a jury question whether a vinyl pool bottom was defective, even if no other commercially reasonable substitute was available. The court held that compliance with the state of the art was but one factor to be considered in applying the risk-utility test. Thus, to reach the jury, "it was not necessary for plaintiff to prove the existence of alternative, safer designs." *Id.* at 306. Would New Jersey's subsequently enacted product liability statute have precluded the result in *O'Brien*? N.J. STAT. ANN. § 2A:58C-3 (West 1987) creates a state of the art defense in subsection (a), but then somewhat softens the effect of that defense in subsection (b), by allowing the court, on the basis of clear and convincing evidence, to find that the product was extremely unsafe, a latent hazard, and virtually useless. If the court so finds, it shall not apply subsection (a). The New Jersey Supreme Court's treatment of asbestos cases is followed in Louisiana. In *Halphen v. Johns-Manville Sales Corp.*, 484 So. 2d 110, 113-16 (La. 1986), the court found that, because asbestos was unreasonably dangerous per se, the defendant would not be heard to argue that it could not know of the dangers of asbestos at the time it was manufactured and marketed.

300. MUPLA, *supra* note 1, § 108 (accompanying analysis). The drafters, sensitive to the problem of governmental immunity, also advised state legislatures to ensure appropriate accountability—although not necessarily through the tort system—before enacting this provision. *Id.*

These burden-shifting presumptions result from the moderate amount of deference the drafters felt such regulations deserved. On the one hand, they placed some stock in sellers' arguments that such standards reflect a good deal of time, thought, and effort, and are often the subject of public scrutiny; that these standards impart welcome consistency and predictability to product liability law; that lay jurors have no business restructuring carefully crafted standards; and that properly conceived standards will supply sellers with an incentive to comply with those standards.<sup>301</sup>

Yet the drafters also recognized the force of counterarguments. First, such standards often result from compromise, and are at times heavily influenced by industry, which has a stake in lowering compliance costs. Second, regulatory bodies may have insufficient personnel or expertise to monitor compliance sufficiently. Third, the government has recognized that its standards are only a minimum; more may be required in order for a product to meet the jurisprudential standard of nondefective.

At this time, compliance (or noncompliance) with regulation should not give rise to a burden-shifting presumption. The drafters' approach effectively constitutes all regulatory agencies as equal, affording a qualified cloaking effect to the determinations of each. Yet the processes by which new products are approved range from strict to lax, with agencies registering at all points on the line.<sup>302</sup> Even those that might be deemed the most cautious and consumer-conscious, such as the FDA, have been criticized for inadequately protecting the citizens who depend on them.<sup>303</sup> Others agencies also have spotty

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301. *Id.* See *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), for a judicial exposition of these points.

302. See generally SUSAN I. TOLCHIN & MARTIN TOLCHIN, *DISMANTLING AMERICAN: THE RUSH TO DEREGULATE* (1983).

303. See Theresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1148 (1988) (criticizing the FDA's and FAA's dependency on data provided by the industries the agency is established to regulate). The article discusses a number of drugs with severe adverse side effects which the FDA approved or failed to regulate properly based on the failure of the manufacturer to inform the agency of dangers of the drugs. In the case of *Merital*, the FDA itself had indications of the severe effects of the drug prior to approving it without providing warnings of such effects. *Id.* at nn.253-55. See also Keith Schneider, *FDA Faulted in Thircat From Animal Drugs*, N.Y. TIMES, Jan. 13, 1986, at A1 (citing congressional report accusing FDA of inadequately monitoring the use of toxic drugs in raising livestock, posing threat to health of consumers); Robin Marantz Henig, *The FDA as Powder Puff: Agency is Called Weak in Regulation of Cosmetics*, WASH. POST, Sept. 27, 1988, at Z12 (criticizing FDA's reliance on "voluntary" oversight of products by cosmetics industry); *Grundberg v. Upjohn Co.*, 813 P.2d at 100 (Stewart, J., dissenting).

records, such as the Consumer Product Safety Commission (CPSC) which has more responsibility for furthering product safety.<sup>304</sup>

Further, an overly deferential approach to regulatory approval neglects the important difference between considering a product *ex ante*, when its most significant dangers may be unknown, camouflaged, or downplayed, and *ex post*, when one or more of those dangers have actually resulted in injury. The regulators, unable to anticipate all that might go wrong with a product, may cast their approving vote without the most significant piece of information—the fact of injury—before them.

On the consumer activist side, this issue of ignorance is intertwined with an incentive problem: While the seller has every incentive to keep compliance costs low (and therefore to press for approval), the consumers' representatives may be operating at an informational disadvantage. Since they may not be able to predict a product's dangers, they may allow products to pass through the regulatory stage without significant opposition. On the consumers' side, the occasion of injury provides both the necessary knowledge and the ultimate incentive to sue. Similarly, consumer advocates are not themselves the injured parties; thus, those with the most at stake are not in a position to protect themselves *ex ante* and should be given their own voice when injury actually occurs.<sup>305</sup>

My criticisms are not meant to sour the promise of regulation. Indeed, comprehensive regulation should be welcomed, as it can prevent a great number of injuries. The EC has recognized the virtue of this two-step approach and promulgated a host of directives aimed at

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304. The CPSC has been described as "an agency racked by dissension and turmoil [which] has virtually abandoned setting mandatory standards . . . . As a result . . . Congress has attempted to pressure it into regulating a number of products that have become hazardous to the public." Schwartz, *supra* note 303, at 1159. These products included "lawn darts, cigarette lighters, all-terrain vehicles, adult sleepwear flammability, and choking hazards in small toy parts." *Id.* at n.196. In 1991, the Institute for Injury Reduction stated in a report that "the CPSC has failed to act aggressively to reduce toy injury hazards; . . . less than 1 percent of all toys [are] ever sampled by the Commission." *Unsafe Toys, Weak Government Regulation cited in IIR report on Toy Injury Hazards*, Daily Rep. for Exec. (BNA) No. 228, at A-11 (Nov. 26, 1991). See also Barry R. Furrow, *The Chain Saw and the Regulator: Inching Toward Safety*, 17 L. MED. & HEALTH CARE 78, 81-83 (1989) (noting the difficulty the CPSC has in proceeding with a mandatory safety standard and suggesting that the agency be given sufficient funds, time to learn, and Congressional support so as "to develop and thrive").

305. To object that the consumer would be better off not suffering injury in the first place is to miss the point. The question here is whether the plaintiff, voiceless during the regulatory process, should have redress when injury occurs.

consumer safety.<sup>306</sup> Most comprehensive among these is the General Product Safety (GPS) Directive enacted on June 29, 1992. That Directive is intended as a sort of wastebasket, to catch those products not covered by more specific directives. The preamble to the GPS Directive acknowledges the futility of attempting to create more specific directives to regulate "every product which exists or may be developed," and governs only "in so far as there are no specific provisions in rules of Community law governing the safety of the products concerned."<sup>307</sup>

An analysis of the General Product Safety Directive is beyond the purposes of this Article. The point is that the European Union has at least attempted a comprehensive regulatory approach by legislating specifically where possible, and has thereby responded to issues unique to particular classes of products. In the remaining cases, the general directive applies. Applied domestically, such an approach could greatly reduce the number of product injuries, which is, after all, the ultimate goal.

#### *d. Postsale Conduct of Claimants and Others*

After establishing a pure comparative responsibility scheme under section 111, the Act defines and explains the kind of conduct that implicates comparative principles in section 112. Such conduct includes not only the manufacturer and the user, but all parties who in some way affect the product on its way from sale to injury.

A provision dealing with nonmanufacturer conduct is necessary in any mature system of product liability. It will be recalled that early product defect cases finding liability typically involved latent defects, usually of manufacture, that passed undetected through the chain of distribution before inflicting injury on unsuspecting product users. If liability were still so limited, it would be sensible to place the entire cost of injury on the manufacturer, or, if unavailable, on another handy seller. But as doctrine developed granting rights to those injured by products that reflected conscious design decisions and announced their own perils, some corresponding apportionment of responsibility among the various sellers and the product user became imperative.

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306. See *supra* note 130 and accompanying text.

307. Council Directive 92/59 of 29 June 1992 on General Product Safety, art. 1(2), 1992 O.J. (L. 228) 24, 26.

Section 112(A), dealing with failure to discover a defective condition, sides with the modern trend in case law: A claimant need not inspect for defects and will not be barred from recovery for failing to do so. The same principle holds for a nonclaimant's failure to inspect. The section's reasoning is supported by one of the fundamental underpinnings of product defect law: A product user is entitled to rely on the product seller to produce a nondefective product, and the "failure," by the claimant or by another, to inspect should not relieve the seller of responsibility for having placed a dangerous product on the market. That same reliance should also shield downstream sellers from negligence-based liability for noninspection since they are not typically in a position to detect the defect.

As noted earlier, this reliance principle is most forceful in the case of a latent defect, where the consumer is truly helpless. The drafters have wisely equated a defect discoverable only upon inspection with a latent defect, since the seller—absent express warning to the contrary—should not be entitled to assume that busy consumers will stop to inspect.

Where the reliance is questionable or absent, the rationale for recovery is weaker. The drafters' treatment of the issue of products with defects recognizes the legal contribution to injury made by those who use a product with a known defective condition. Therefore, where the seller proves that the claimant knew of such a condition but went ahead and used the product anyway, recovery may be reduced under comparative principles: "Thus, if a claimant with good eyesight ate a candy bar that had bright green worms crawling over it, subsection (A)(2) permits the trier of fact to find that the claimant should bear some responsibility . . . ." <sup>308</sup>

As to a nonclaimant product user's failure to inspect, the drafters demurred; subsection (B)(2) to section 112, which allows apportionment of liability between manufacturers and such users, is optional. To illustrate the close balance of equities that led to this hedged result, consider a case arising in the workplace. If a piece of industrial machinery goes uninspected by the employer, and an employee is then injured as a proximate result, should the employer bear a share of the responsibility? On the one hand, such an approach would place the incentive to inspect machinery on the employer. On the other hand, the shield of worker's compensation acts to blunt that incentive. If liability is apportioned wholly against the employer by a trier of fact,

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308. MUPLA, *supra* note 1, § 112 (accompanying analysis).

the product-injured user may be out of the tort system entirely. One solution would be to allow apportionment, but not to allow the manufacturer's liability to be reduced to zero. In such a case, the Act's rule of joint and several liability would ensure that the manufacturer would always be liable, and that other culpable parties would also face tort liability unless they were entirely exempt from the system.

Subsections (C) and (D), which deal with the related issues of product misuse and product alteration, are found lacking in one significant respect. Misuse of a product under subsection (C) causes a reduction of the seller's liability to the extent that the misuse caused the injury. If the claimant is the misusing party, recovery is simply reduced; a nonclaimant's misuse instead shifts the plaintiff's target, in whole or in part, to the misuser. Of course, product misuse may be so dramatic that liability is entirely improper because the injury would then have been caused by the misuse, not by the product.

As to product alteration, subsection (D) differs from its sister provision on misuse in that the reasonableness of the alteration drops out of the equation. Thus, once the product seller shows that modification of the product, either by plaintiff or by some third party, caused the injury, liability is reduced to the extent that such modification caused the harm. In opting for this blanket rule, the drafters recognized that they were departing from the ascendant common law view under which "foreseeable" modifications might not defeat liability. Their justification for doing so was that holding sellers liable under such circumstances amounted to imposing "absolute liability."<sup>309</sup>

This reasoning is riddled with flaws. First, the drafters do not explain why the treatment of modifications should differ from that of misuse; such an explanation is called for if these two related, postseller actions are to come in for different treatment. Second, it is simply incorrect to assert that the foreseeability test leads inexorably to liability. Courts have been willing to find that product modifications were unforeseeable,<sup>310</sup> and also have declined to find liability where the producer of the product had no realistic way of preventing the kind of modification that caused harm—even where the modification was foreseeable.<sup>311</sup> Finally, the simple statement that the foreseeability test imposes absolute liability, even if it were correct, is not a suffi-

309. MUPLA, *supra* note 1, app. A, § 112 (accompanying analysis).

310. *See, e.g., Ford Motor Co. v. Eads*, 457 S.W.2d 28 (Tenn. 1970).

311. *E.g., Robinson v. Reed-Prentice*, 403 N.E.2d 440, 443 (N.Y. 1980) ("Principles of foreseeability . . . are inapposite where a third party affirmatively abuses a product by consciously bypassing built-in safety features.").



cient reason for doing away with it. What is needed is an explanation of why that result is undesirable, particularly since it is welcomed in other contexts, notably with respect to manufacturing defects.

For the sake of completeness, I should point out that the drafters do provide a few caveats to the broad rule discussed above. Where the manufacturer instructs the user to modify the product, or where consent is given—even impliedly—to so modify, the no-liability rule of subsection (D)(2) will not apply. Nor will that subsection apply if the modification was “reasonably anticipated conduct,” from the perspective of a reasonably prudent person under the circumstances,<sup>312</sup> but *only if* the product seller should have warned against such modifications under subsection 104(C).

Unfortunately, this approach recapitulates the more general weakness of any attempt to create a substantive body of product liability rules *ex ante*. On one level, the apparent clarity will be defeated once the first case arises in which, for example, the court must decide whether a manufacturer’s conduct amounted to implied consent to the modification. On a deeper level, a claimant’s inability in any given case to shoehorn the claim into one of the recognized exceptions to the no-liability rule may result in injustice (i.e., where a reasonable product user or a reasonable third party might have nonetheless modified the product).

## 2. MUPLA’s Effect on the Conduct of Litigation

The rush toward codification of the substantive rules of product liability should be viewed skeptically. Indeed, the drafters of both the Act and the Directive have, for the most part, been suitably wary of anticipating possible product problems. The substantive sections are therefore largely open-textured; the bulk of my criticisms concern provisions that may unwisely restrict judicial pliability.

However, the movement toward clarifying, streamlining, and unifying the law of product liability is commendable. To begin with the broadest issue, uniform legislation would bolster confidence in the judicial system’s ability to produce consistent results. Such uniformity can of course be achieved directly, as through an act of Congress. Both the Directive and the Act have opted instead for a two-layered approach, involving promulgation of rules by a central entity, followed by implementation in member jurisdictions.

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312. MUPLA, *supra* note 1, § 102(G).

Regardless of the chosen method, my preference for uniformity extends to substantive results as well as to procedure. This position is not inconsistent with my skepticism of *ex ante* rule-making on the substantive issues of product liability. Whether the issue at hand is one of procedure (lending itself to *ex ante* regulation) or of substance (better treated by courts, *ex post*), there should be at least a tentative end to the matter once the question has been answered in the appropriate manner.<sup>313</sup>

Once a decision is reached that a product is, or is not, defective—again, something difficult to ascertain before injury—that determination should not ordinarily be disturbed by another court. Otherwise, the *de facto* regulation that inevitably occurs will be patchwork or, worse, inconsistent. Manufacturers will thereby be forced to guess as to which of two or more inconsistent decisions should guide their future conduct. A dramatic example of the problems created by such inconsistency is the maze of decisions involving the drug Bendectin. As Professor Shapo has recently pointed out,<sup>314</sup> the issue of whether the drug is capable of causing serious birth defects has received inconsistent answers by different courts over the past few years.<sup>315</sup> Since the answer to that question determines whether the drug is defective under a consumer expectation model, a definitive answer would allow both future plaintiffs and the manufacturer, Merrell Dow, to avoid further litigation and to have some idea of their financial futures.<sup>316</sup>

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313. The qualification is needed because, as with any line of cases or regulation, changed circumstances or evolving notions of justice may call for a reconsideration of any decision. But such reconsideration can be accomplished through the standard means of legislative amendment or overruling of precedent. Indeed, the sober reflection that attends, or should attend, such steps attests to the weight that these decisions are accorded and deserve.

314. Shapo, *supra* note 107, at 314-15.

315. Compare *Richardson v. Richardson-Merrell*, 649 F. Supp. 799 (D.D.C. 1986) and *Lynch v. Merrell-National Lab. Div. of Richardson-Merrell, Inc.*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987) (finding no sufficient proof of causal connection as a matter of law) with *Oxendine v. Merrell Dow Pharmaceuticals*, 506 A.2d 1100 (D.C. Cir. 1986) and *DeLuca v. Merrell Dow Pharmaceuticals*, 911 F.2d 941 (3d Cir. 1990) (testimony by a single expert sufficient to establish a factual issue of causation). The United States Supreme Court has recently rewritten the test for admissibility of scientific expert testimony under the Federal Rules of Evidence, holding that admissibility requires a determination by the trial judge that the expert will testify to scientific knowledge that will assist in the understanding or determination of an issue of fact. *Daubert v. Merrell Dow Pharmaceuticals*, 113 S. Ct. 2786 (1993).

316. Consolidating cases can be of enormous assistance in this task. See e.g., *infra* note 357 (cases consolidating the *Suzuki Samurai* litigation).

When the issues involved are procedural, comprehensive legislation can profitably go beyond placing cases under one judicial roof. With the limited exception of provisions relating to statutes of repose, most of the major issues that go into designing procedural rules can be addressed *ex ante*. In this regard, the Act is superior to the Directive, addressing and resolving a host of thorny procedural problems. In addition, the commentary accompanying the procedural provisions indicates that the drafters considered both sides of each argument. Although emphatically *not* the situation with substantive questions, which shift subtly between cases, broad decisions can be made as to the matters of procedure. Such rule-making is in fact desirable, as it furthers predictability and certainty without any corresponding sacrifice of fairness.<sup>317</sup>

The present subsection differs from my comprehensive treatment of the Act's substantive provisions. Here, I address only selected issues arising under the procedural sections of the Act. Many of these sections are self-explanatory, borrowing from other legislation and from current judicial practice.

For example, the Act includes provisions for sanctions against frivolous claims and defenses;<sup>318</sup> retains the rule of joint and several liability;<sup>319</sup> expressly allows the court to appoint its own experts;<sup>320</sup> causes reduction of recovery under the collateral source rule only to the extent that the claimant has received compensation from a public source;<sup>321</sup> contains an optional provision limiting nonpecuniary damages to \$25,000, "or twice the amount of the pecuniary damages, whichever is less;"<sup>322</sup> and retains punitive damages upon a showing of at least reckless conduct.<sup>323</sup> The procedural sections also contain a

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317. This preference for unified rules of procedure is not meant as an endorsement of any one rule, or of the entire package, as drafted. My agreement is rather with the process of case disposition that the rules foster.

318. MUPLA, *supra* note 1, § 115.

319. *Id.* § 111(B)(5). Liability is only several, however, "when a party is responsible for a distinct harm, or when there is some other reasonable basis for apportioning that party's responsibility for the harm." *Id.*

320. *Id.* § 117(A).

321. *Id.* § 119.

322. *Id.* § 118(C). The optional recovery limitation provision will not apply when a claimant suffers "serious and permanent or prolonged (1) disfigurement, (2) impair[ment] of bodily function, (3) pain and discomfort, or (4) mental illness," and proves these injuries by a preponderance of the evidence. *Id.*

323. *Id.* The court decides the amount of such damages after the jury decides whether to impose them.

welcome change in the typical treatment of the relation between worker compensation law and product liability law.<sup>324</sup>

None of the drafters' decisions is immune from criticism. Some commentators have argued, for instance, that retaining joint liability is inconsistent with the principles underlying comparative responsibility—that each party should pay only according to its share of culpability. And the drafters themselves recognize that their position on the collateral source rule represents a compromise that can be attacked on both flanks. On one side are those who favor reduction of recovery, from whatever source derived; arrayed in opposition are those who fear the loss in deterrence by allowing collateral source reduction.<sup>325</sup>

For the most part, I leave to the reader consideration of the forces that have led to the procedural rules adopted under the Act. The drafters have generally understood and appreciated the arguments on both sides of these issues and have tried to come up with the best possible solutions. Returning again to the collateral source rule by way of example—the decision to permit reduction of recovery to the extent that the claimant has been reimbursed through public sources reflects the perception that, as to such funds, the public would end up paying a double cost—the product seller contributes to the public funds from which the claimant draws, increases prices accordingly, and pays the claimant's judgment, thereby increasing prices twice. Thus, collateral source recovery under MUPLA does not diminish plaintiff's recovery *except* where the sources are public funds.

Leaving to the political process the judgment about where to draw these lines, I discuss here only those procedural issues that bleed into substance, and where the drafters have then imposed strict rules, namely, the time limitations imposed on actions.

Section 110 of the Act deals with related issues concerning the time limitations on product liability actions. To begin with the least controversial provision, subsection (C) sets the statute of limitations at two years but holds off the commencement of that period until "the claimant discovered, or in the exercise of due diligence, should have discovered, the harm and the cause thereof." This language is typical of that found in modern tort law<sup>326</sup>—the plaintiff is not penalized for failing to know the unknowable.

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324. See *infra* subpart V.C.

325. MUPLA, *supra* note 1, § 119 (accompanying commentary).

326. See *Teeters v. Currey*, 518 S.W.2d 512, 517 (Tenn. 1974) ("[W]here medical practice is asserted . . . the cause of action accrues and the statute of limitations begins to run

Further, the requirement highlights that the plaintiff must understand both injury *and* causation. Not all products that cause harm follow the model of the exploding bottle, where causation can be directly and immediately assigned to the offending product. Consider the claimant who experiences a rare side effect from a pharmaceutical. If the symptoms are nonspecific, it may take some time for the claimant to link his harm to the drug, especially if his doctor is also without sufficient knowledge. Assuming plaintiff's due diligence in unmasking the connection, the statute correctly decides that recovery should not be foreclosed.<sup>327</sup>

Somewhat more novel is subsection (A), which allows the product seller a defense where the product caused injury after its "useful safe life" had expired. The subsection, drawn from a state statute,<sup>328</sup> recognizes that a product may, because of age or overuse, cause an injury without being defective. The drafters cite the helpful example of a driver who continues to drive on worn tires. The product may still be "useful," but it is no longer "safe." When that tire punctures, injuring plaintiff, the product seller should be able to argue that the product had exceeded its useful safe life.

Wisely, the drafters chose not to pin the determination of "useful safe life" to any specific time period, recognizing that products exhibit wide variation in this regard. The subsection supplies examples of probative evidence,<sup>329</sup> but avoids bright-line tests. Significantly, the seller's representations and instructions as to the care and feeding of the product, and the issue of useful safe life are given considerable weight, but they are not dispositive. The drafters sided with the courts, recognizing that to allow the seller unchecked power in determining a product's safe life would be to oversimplify the issue of whether the product's user acted reasonably in exceeding the stated time period. Also, such pronouncements by the seller should "not

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when the patient discovers, or in the exercise of reasonable care and diligence . . . should have discovered the resulting injury.").

327. Although this result seems obvious, the language of section 110 can have the beneficial effect of preventing a court from throwing the plaintiff out of court for failure to comply with the statute of limitations, even where a reasonable person would have been unable to connect his or her injury with the defendant's conduct. *See, e.g., Greco v. University of Delaware*, 619 A.2d 900 (Del. 1993) (medical malpractice).

328. In the analysis accompanying section 110, the drafters credit MINN. STAT. ANN. § 604.03 (West 1988) as providing the inspiration for section 110(A) of the MUPLA.

329. *See* MUPLA, *supra* note 1, § 110(A)(1)(a)-(e).

bind the rights of a non-purchaser claimant" who would be unaware of such statements.<sup>330</sup>

The problem with section 110 is subsection (B). Simply put, once the product is more than ten years beyond delivery, the seller receives the benefit of a very strong presumption that the product has exceeded its useful safe life. "The presumption may only be rebutted by clear and convincing evidence."<sup>331</sup> The subsection then softens the impact of this harsh rule through a series of exceptions. The expected, noncontroversial exceptions include: express warranties of longer safe lives; intentional misconduct on the seller's part, which renders the limitation void; and any remaining rights to contribution and indemnity, which are not affected by the presumption.

Further substantial limitations to this seller-friendly presumption reside in subsection (B)(2)(d). The drafters follow the prevailing trend by placing the long-term exposure cases outside the statute's reach. Thus, where injury is the cumulative result of prolonged exposure, as with workplace toxins, or if the injury takes many years to manifest itself, as is the case with DES,<sup>332</sup> the presumption does not apply. Although the drafters do not explain their reasoning for these sensible exceptions, they are easily justified. Where the product's very nature precludes identification of defect until more than ten years have passed, that accident of science should not place the seller in a better position than its counterparts who sell products with more obvious defects.

Somewhat more cryptic is subsection (B)(1)(d)'s exception for injuries caused by defects that were "not discoverable by an ordinarily reasonable prudent person until more than ten . . . years after the time of delivery." The drafters explain this language by citing the case of defective plastic on a gearshift that only manifested itself after expo-

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330. *Id.* § 110 (accompanying analysis).

331. *Id.* § 110(B). This approach is actually quite unusual. In most states, where a statute of repose applies, the claimant's case is flatly barred. *See, e.g.,* OR. REV. STAT. § 30.905 (1987) (exception for asbestos-related claims); TENN. CODE ANN. § 29-28-103 (1989). The drafters of MUPLA followed the Colorado model instead, COLO. REV. STAT. ANN. § 13-21-403 (3) (West 1989), and afforded the seller a *presumption* of no liability. This more limited approach is more likely to survive constitutional challenge. For a collection of cases dealing with the constitutionality of repose statutes, *see* DAVID A. FISCHER & WILLIAM POWERS, JR., *PRODUCTS LIABILITY: CASES AND MATERIALS* 685-86 n.1 (2d ed. 1994) (cases going both ways on the issue).

332. DES is short for diethylstilbesterol. Once marketed as a means of combatting miscarriage, DES has been accused of causing a host of illnesses and other problems in the daughters of the mothers who ingested it. *See, e.g., Sindell v. Abbott Lab.*, 697 P.2d 924 (Cal. 1980); *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y. 1989).

sure to sunlight occurring more than ten years after delivery. Presumably, this exception is intended to apply only in those cases where the product is a "time bomb" of sorts that only "goes off" after more than ten years, and after the dangerous condition has finally been activated. Further, this exception only applies when the user had no knowledge of the inherent dangers in the product.

What effect would this subsection have on a more typical case, where the product causes injury in such a way that it is unclear whether the injury was caused by a defect, or by use of the product beyond its useful safe life? The Act's strict statute of repose was probably created with exactly that sort of case in mind. So, for example, if a passenger is injured on an airplane that had been in service for more than ten years, any claim against the product seller would have to contend with the presumption that the product had exceeded its useful safe life.

This result is unacceptable. Products such as airplanes, industrial equipment, and many durable household appliances have useful safe lives that plainly exceed ten years. The consumer injured beyond that point should not be forced to present clear and convincing evidence to rebut the presumption of no liability. The Act is, however, preferable to state statutes which impose an absolute statute of repose, and the drafters did make note of the consumers' "justifiabl[e] concern . . . about overly broad absolute cut-offs of their right to sue."<sup>333</sup>

Nonetheless, for products with long useful lives that cause injury through long-term exposure, the Act ends up doing what it tries to avoid with toxic exposures—it gives sellers of more durable products an undeserved advantage over those who sell products with shorter useful lives.<sup>334</sup> The section should have been omitted entirely<sup>335</sup> in

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333. MUPLA, *supra* note 1, § 110 (accompanying analysis).

334. Thus, the arguments for permitting such a presumption must come from the more general reasons offered to justify such statutes. These are succinctly set forth in VINCENT R. JOHNSON & ALAN GUNN, *STUDIES IN AMERICAN TORT LAW* 789 (1994).

335. For a recent article advocating a more flexible approach to the issue of repose in product liability cases, see Mark W. Peacock, *An Equitable Approach to Products Liability Statutes of Repose*, 14 N. ILL. U. L. REV. 223 (1993). However, because Professor Peacock makes his assumptions in a world where statutes of repose are acceptable in principle, his proposal would not assist the plaintiff in many cases. His concern is to create an exception for the cases where the manufacturer "misrepresent[s] its product or fraudulently conceal[s] . . . its knowledge of the unreasonably dangerous and defective condition of its product to the detriment of the consumer . . ." *Id.* at 224. One might think that such a reasonable position would already have enjoyed wide judicial favor; in fact, as he points out, the majority of courts have not recognized an exception to statutes of repose even

favor of the provisions governing exposure to slow-acting environmental toxins.

## V. Application of Rules and Principles of the Directive and the Model Uniform Product Liability Act

The promulgation of the Directive holds promise for a consistent body of product liability law on both sides of the Atlantic. Movement in the direction of consistency depends, in part, on the extent to which the nations of the European Union select the same options in cases where the Directive provides a choice. Beyond that, the judiciary's role should not be underestimated. One of the goals of this Article has been to demonstrate that the rules, particularly of substance, cannot truly begin to be assessed until the courts have interpreted them.

Inasmuch as constructions of rules relating to the conduct of litigation are generally simpler to predict than are constructions of the substantive rules of liability, one regrets that the Directive has unfortunately not developed its procedural rules as fully as has the MUPLA. It is too much to expect that such rules, even when developed, will be fully consistent with those in force in the United States. After all, even those states that have based their legislation on MUPLA exhibit important divergences in enactment. Yet, one need think only of jurisdictional problems to recognize that attempts at achieving consistency are worthwhile. To give just one example: Bob, a resident of Philadelphia, purchases an automobile assembled in Illinois. A defective belt tears loose, and his car veers out of control, thereby injuring Bob. The belt is manufactured in Germany and the automotive company is a joint venture between a German and an American manufacturer.

Much of the wrangling over jurisdiction in such a case might be less portentous if the basic procedural rules approached uniformity.<sup>336</sup> In both the United States and Europe, these matters are properly left to the political process, with the legal academia and citizens' groups

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where the equities are clear. *Id.* at 237 (citing cases at n.67). MUPLA, however, would recognize this equitable exception. *See supra* note 329.

336. As mentioned earlier, there will remain a host of problems that might overwhelm any advantage gained by streamlining the procedural course of such a case. The unassailable facts that the suitor before a domestic court enjoys structural advantages not enjoyed by her European cousin, and can usually count on a more substantial recovery, suggest that the divergences can only be overcome by looking beyond a particular field of law.



standing by to ensure that the rights of injured citizens are not unfairly compromised.<sup>337</sup>

The balance of this final section is devoted to a consideration of the ways in which courts—here and abroad—might approach the issue of defect, which is at the heart of the greatest number of product liability cases. Unfortunately, no elegant theory is at hand for resolving this question in every case. About the best that can be done here is to canvas a representative sample of different types of defective products.

In each case, I discuss the approach and, to the extent predictable, the likely result under both the Directive and MUPLA. I then provide commentary as to which, if either, of the approaches provides a better chance for a just result, and offer observations that might be useful in resolving the case. My assumption throughout is that the guiding principle should be the consumer's expectation, either actual or by inference where not directly ascertainable.

### A. *Simple Defects of Manufacture*

A chair is fashioned with a bolt of defective metal. The chair, newly purchased by Alice, collapses and causes her serious injury. The metal defect is proven by uncontradicted testimony of metallurgic experts who testify that other chairs by this manufacturer were constructed of stronger metal, and that this chair's bolt contained impurities at the microscopic level.

Why bother discussing this case at all? Under both the Directive and under *all* competing legislation, actual and contemplated, in the United States, this defect of manufacture calls for strict liability. The Directive's imposition of liability for products more dangerous than the "consumer has a right to expect" applies. Further, even under domestic proposals and enactments that apply the risk-utility test to defects of design, manufacturing defects are left in the realm of true strict liability.

Yet the concession by the drafters of MUPLA and similar legislation—notably including the proposed revision of section 402A—that liability for manufacturing defect should be strict suggests that the underlying justification for liability is inconsistent. Liability in the manu-

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337. As pointed out in subpart II.A, *supra*, civil-law countries have a long heritage of deferring to the professoriate. Although this tradition is not established with respect to Directives, perhaps such an approach could assist in just resolutions of disputes over the interpretations of specific provisions.

facturing defect context is necessarily based on consumer expectation; the consumer is powerless and caught unaware. It is also true that the manufacturer could *in general* prevent the injury more easily than the consumer. Thus, the risk-utility calculus would generally favor the plaintiff as well. But this is not always the case, especially when one considers the costs in making absolutely certain that no defective products slip through the manufacturing process. In fact, since absolute certainty borders on the theoretically impossible, risk-utility is *not* the theory being applied.

One explanation for the inconsistency between the theory underlying recovery for manufacturing defect and the approach taken in the rest of the cases involves the practical problems in the risk-utility approach when applied to manufacturing problems: Defects are isolated and hard to prove. But that explanation is belied by the legislative history of the various enactments, which reflects the perception that the true strict liability approach in the manufacturing defect cases is simply fairer to the consumer who is assumed to be helpless to prevent or predict injury.<sup>338</sup>

Since it is clear that liability in the manufacturing defect cases stems from a consumer expectation model,<sup>339</sup> it is lamentable that the "reformers" did not carry this insight into at least those cases of design defect where the consumer is equally helpless. Returning to *Greenman*,<sup>340</sup> why should the theory of liability, and potential recovery, turn on whether the defect was of manufacture or of design? The proper focus should be on *Greenman*'s reasonable expectation that the set screws were sufficiently strong to do the jobs for which he purchased the tool. The considerations of justice that seem to have impelled recovery for those injured by defects in manufacture apply just as strongly where the unsuspecting plaintiff is injured because the defendant decided, applying a risk-utility weighing, to forego the use of a stronger screw, (*i.e.*, the tests to uncover defects in screws). Yet because this case falls within the literal definition of design defect, the manufacturer might be able to escape liability where the incidence of

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338. Henderson and Twerski admit as much, in remarking that "[c]onsumers injured by flawed products argue that their fundamental expectations as to product performance have been disappointed." Henderson & Twerski, *supra* note 2, at 1516. Why haven't these same expectations been disappointed when the product turns out to have a latent defect in design, for example?

339. Indeed, the drafters of the proposed revision of Restatement (Third) of Torts section 402A have noted that the original section 402A was mostly concerned with defects of manufacture, where the consumer expectation model governed.

340. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897 (Cal. 1962).

injury would be lower than the anticipated cost of compensating the few who might be injured. But surely this hidden defect should call for liability, notwithstanding cost-benefit considerations.<sup>341</sup>

A more recent example of defects of an uncertain type might be the pedicle screw inserted into the backs of people with chronic pain. It now appears that the screws may actually be increasing pain, perhaps because some of them seem to have broken in the users' backs.<sup>342</sup> Under MUPLA and the Restatement (Third) approach, recovery might be granted or denied based on caprice: Whether the defect is called one of manufacture or of design. Under the consumer expectation model, the nature of the defect would be relevant only to the extent that it illuminated the central issue of the communications between seller and user. For instance, if the problem of breaking screws was consistent and known but inevitable, and that possibility and its consequences were clearly communicated to a potential user, recovery might reasonably be denied. If, on the other hand, breaking screws were unexpected at the time of insertion, the consumer's defeated expectation of reasonable safety might properly permit recovery.<sup>343</sup>

In attempting to track down representations made to users, the pedicle screw liability issue is further complicated by the intervention of surgeons. As one article states, these devices were "touted as state of the art by many surgeons."<sup>344</sup> Further, doctors appear to have been using the screws in a manner not approved or contemplated by the FDA, or perhaps even by the manufacturers.<sup>345</sup> To the extent that

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341. Professor Phillips has noticed the same inconsistency in the Proposed Restatement (Third) of Torts: Product Liability: "[The Reporters] . . . recognize that the representational aspect of products liability is an essential part of the consumer expectations test . . . which the Reporters are particularly anxious to reject." Jerry J. Phillips, *Achilles' Heel*, 61 TENN. L. REV. 1265, 1268 (1994). But, this rejection does not extend to manufacturing defects, which the Reporters admit "disappoint reasonable expectations as to product performance." *Id.* at 1269 (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Council Draft No. 2, 1994)). As he notes, "[s]urely these rationales apply equally to design and warning defects." *Id.* at 1270.

342. *FDA Hears Complaints on Spinal Screws*, CHI. TRIB., July 23, 1994, at 16.

343. Even these two brief examples suggest the error in segregating the so-called manufacturing defect cases since they imply that the line between manufacturing and design defect may at times be difficult to draw. What if the screw breaks only when it is subject to unusually heavy exertion? What if it does not always break under that circumstance?

344. Susan Fitzgerald, *Spine-Fusion Surgery Backfiring for Many*, PHILADELPHIA INQUIRER, July 18, 1994, at A1.

345. The FDA had approved them only for "repairing bones in the arms and legs . . ." This same article mentions two manufacturers of the screws, AcroMed Corp. and Sofamor Danek Group Inc., both of which, it notes, have been sued in a class action. *Id.* at A6.

consumer expectations arise from a course of communication with their physicians, and not from any representations by the manufacturer, liability might properly lie only with the doctors. In an important sense, these surgeons could be viewed as "creating" a product of their own—pedicle screws used for a new purpose.<sup>346</sup>

Operating in a risk-utility universe, the drafters could only separate the manufacturing defect cases for special, "true" strict liability, treatment, thereby missing nuances that create the need for judicial intercession in the first place. The consumer expectation approach favored by the Directive avoids this forced dichotomy, instead emphasizing the need to pick through the complexities of the bargain struck, often through implicit communication between buyer and seller.

The problem with the risk-utility test is most forcefully demonstrated in the manufacturing defect cases where the theory is abandoned because of its inability to achieve justice. But across the much broader spectrum of design defect and failure to warn cases, focus on the consumer's expectation, rather than application of an unreconstructed risk-utility test, repeatedly results in outcomes more consistent with the requirements of justice. The remainder of this section considers a few representative categories of products with problems—automobiles, industrial equipment, and pharmaceuticals—which call into question such diverse issues as the state of the art defense, the connection between defect and warning, the special problem of unavoidably unsafe products, and the difficult issues of causation that the enactments address but do not advance.

In each class, a discussion of cases will be accompanied by an analysis of the relevant provisions of the Directive and of the MUPLA. I will then offer further observations. The aim is not simply to convince the reader of the superiority of the consumer expectation approach,<sup>347</sup> but to highlight various problems with other rules set down by either of these liability schemes.

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346. Fitzgerald notes that "[d]octors often adapt drugs and techniques to situations for which they are not specifically marketed—an 'off-label' use." *Id.* Of course, a factual investigation would be needed to determine the extent to which the manufacturers, individually or collectively, might have encouraged these "off-label" uses. Depending on the results of such an investigation, they too might be liable.

347. Indeed, the risk-utility test can be of some value in determining liability, but only insofar as it feeds into the consumer's reasonable expectation of the product's safety.

### ***B. When is an Automobile Defective?***

The threshold difficulty in most automobile cases is that the offending vehicle is alleged to be defective not because it spontaneously explodes, but because it affords less protection in an accident—is less “crashworthy”—than the injured occupant expected. The exploding car presents an easy case, mainly because of the helplessness of the properly relying consumer. Of course, under the system instantiated by MUPLA, inquiry into risk-utility would be needed before liability could attach.

The crashworthiness cases illustrate the troubled relation between regulation, legal doctrine, and plain fact that plagues product liability. As illustrated by these cases, prediction and easy rules are beguiling but misguided.

The simplest crashworthiness cases involve design problems that are hidden, unknown to the class of consumers, and not directly regulated. In *Robinson v. Audi NSU Auto Union*,<sup>348</sup> an Audi was struck from behind by a speeding Ford. The fuel tank, which was located under the floor of the Audi's trunk burst into flames, severely burning the occupants. The matter was tried by jury under the Tenth Circuit's approach, in which the consumer's reasonable expectation was dispositive in deciding the liability issue. Although the plaintiffs might have been expected to succeed on that basis, their attorneys may have (paradoxically) lost the case by introducing evidence of other available design alternatives at the time of manufacture. This maneuver, the court stated, opened the door for the defendant's argument that Audi had followed general industry practice. Such practice was “relevant . . . to the determination of the expectations of the consumer . . . .”<sup>349</sup>

Without a special verdict, it is impossible to divine the basis of the jury's decision that the car was not defectively designed. Perhaps the jury thought that since the gas tank had to be *somewhere*, the industry's custom made sense absent a showing that the custom represented a decision to sacrifice safety for reasons of cost. Alternatively, perhaps the suggested design alternatives would be more dangerous in most cases and courts have properly required that a product's entire design be considered in making decisions regarding defect.<sup>350</sup>

In short, the jury's decision may well have been faithful to the consumer expectation test. The consumer does, or should, expect a

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348. 739 F.2d 1481 (10th Cir. 1984).

349. *Id.* at 1485.

350. *See, e.g.,* *Wilson v. Piper Aircraft Corp.*, 577 P.2d 1322, 1327-28 (Or. 1978).

product that is, all things considered, as safe as can feasibly be made. This expectation certainly holds true where the consumer's knowledge is weak or absent compared to the seller's. Risk-utility considerations may illuminate this issue, but should be in service of it; not the other way around, as MUPLA would have it.<sup>351</sup> Of course, if a manufacturer had actual knowledge of a high degree of risk of an explosion and deliberately chose to withhold that information, liability would be proper under a theory of criminal fraud.<sup>352</sup>

The decision where to place the fuel tank, when any choice brings some degree of risk, stands on different footing from the defect alleged in *Larsen v. General Motors Corp.*<sup>353</sup> There, a head-on collision resulted in the steering column of the plaintiff's Corvair striking the plaintiff's head. The plaintiff introduced testimony to show that the Corvair's steering mechanism, unlike that of other cars, was positioned so that "it receive[d] the initial impact of forces generated by a left-of-center head-on collision. The unabsorbed forces of the collision in this area [were] transmitted directly toward the driver's head . . . ."<sup>354</sup>

Absent some good reason for placing the steering column in an apparently dangerous position—a place other car manufacturers avoided—liability for such an injury should be simple: the plaintiff reasonably expects that the car will not be fatally unsafe in a way that could have been, and was, avoided by other manufacturers.<sup>355</sup> By focusing on the right to safety the consumer "is entitled to expect," the

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351. See MUPLA, *supra* note 1, § 104 (accompanying analysis).

352. Cf. *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 360 (Cal. Ct. App. 1981) (finding that Ford knew of the dangers that a rear-ended Pinto would explode, but chose not to redesign the car anyway; punitive damages were therefore appropriate).

353. 391 F.2d 495 (8th Cir. 1968).

354. *Id.* at 497 n.2.

355. Of course, it is assumed that the defectively placed steering column was the legal cause of plaintiff's injuries. In *Berrera v. Hyundai Motor America Corp.*, 620 So. 2d 890 (La. Ct. App. 1993), plaintiffs alleged that a defective seat track latching mechanism increased their injuries. The jury credited the defense expert's testimony that "the principles of biokinematics demonstrated that plaintiff's theory was a physical impossibility." *Id.* at 895.

All product liability law, judicial and legislative, requires a showing of causation. Again, the Directive imposes liability for a damage "caused by a defect." Council Directive 85/374 art. 1, 1985 O.J. (L 210) 29, 30. MUPLA is equally explicit, requiring that liability for a defect of any kind be imposed only where "the harm was proximately caused because the product was defective." MUPLA, *supra* note 1, § 104. Courts have occasionally been sensitive to the problems of proof in manufacturing defect cases, allowing the plaintiff a presumption that the product was defective (and so that the defect was the cause of injury), where tracing the creation of the defect to the manufacturer presents too high a hurdle. See, e.g., *Jagmin v. Simonds Abrasive Co.*, 211 N.W.2d 810 (Wis. 1973).

consumer expectation test and the Directive achieve the right result here. Under the risk-utility test the defendant might still prevail by showing that costs were kept down by placing the mechanism in this dangerous place.

Particularly where the defect is latent and no regulation specifically applies, the consumer's safety should not be bargained away so cheaply. Indeed, it is fundamentally wrong to say that the consumer has bargained at all as to the safety issue in this case. Unaware of the problem with the steering column, how can it be said that the consumer willingly sacrificed safety for lower cost?

These two cases are relatively simple because the defects are incontrovertibly latent. No bargain as to that particular safety feature took place, therefore the question is whether the manufacturer properly attended to the consumer's safety in designing the vehicle. But most cases are more complex, making the question of consumer expectation more troubling.

The issue of vehicle rollover supplies a lively example of the intersection of politics, regulation, marketing, consumer behavior, and jurisdiction that often complicates the resolution of design defect cases. Design defect claims relating to rollovers involve vehicles alleged to roll over too easily, because of their center of gravity, or roofs that are not strong enough to withstand the impact when the car does roll over. This second set of cases is simpler to resolve, because it generally involves latent defects, where the consumer could not know what the roof would do in case of impact.<sup>356</sup>

The first set of claims, currently in litigation throughout the country,<sup>357</sup> has most notoriously involved the Samurai, a small, inexpen-

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356. See, e.g., *Shipp v. General Motors Corp.*, 750 F.2d 418 (5th Cir. 1985) (roof over driver's seat collapsed). A somewhat more difficult case was presented in *Reed v. Chrysler Corp.*, 494 N.W.2d 224 (Iowa 1992), where the court overturned a directed verdict for defendant. The plaintiff's theory of design defect was that the roof should have been made of metal, not of fiberglass. Although the fiberglass construction of the roof was obvious to the plaintiff, the increased risk posed by fiberglass may not have been so apparent. And what should be done about the fact that the vehicle in which plaintiff was travelling had, at the time, "the only plastic top sold in North America?" *Id.* at 228. Without an express showing that the vehicle was sold cheaply because of its unique top, the prevailing industry custom should suggest culpably poor design.

357. See, e.g., *Malautea v. Suzuki Motor Co.*, 987 F.2d 1536 (11th Cir. 1993) (upholding trial court's imposition of liability as sanction for repeated discovery abuses); *Marlow v. American Suzuki Motor Corp.*, 584 N.E.2d 345 (Ill. App. Ct. 1991) (providing a flavor for the procedural complexities that attend multidistrict litigation); *In re Suzuki Samurai Prod. Liab. Litig.* No. 784, 1988 U.S. Dist. LEXIS 17014 (J.P.M.L. Nov. 29, 1988) (transferring eleven pending actions to the Eastern District of Pennsylvania).

sive, four-wheel-drive vehicle manufactured by the American Suzuki Motor Corporation (Suzuki).<sup>358</sup> The vehicle gained unwanted press as far back as July 1988, when Consumer Report rated it "Not Acceptable" for public purchase, "the first such rating that the group had given to an automobile in ten years."<sup>359</sup> In the wake of such bald condemnation by a respected consumer watchdog, one might have expected the National Highway Traffic Safety Administration (NHTSA), a federal agency, to have recalled the cars. It did not. Nor did the NHTSA subsequently regulate the vehicles into a safer configuration. Its response was instead to attack the Center for Auto Safety for undermining "public confidence in [NHTSA's] ability to pursue safety defects . . . ."<sup>360</sup> The Center, a nonprofit organization, had been alerting the public to auto defects, including that presented by the Samurai.<sup>361</sup>

Further smudging the picture, documents unearthed during litigation disclosed that General Motors, having learned by its own testing of Samurai's unacceptable propensity to roll, had declined Suzuki's invitation to market the vehicles, as early as April 1984.<sup>362</sup> Suzuki apparently recognized that the vehicle's structure, originally designed for off-road driving, posed risks under routine driving conditions. As a Suzuki official put it, the company "decided to let consumers determine for themselves what this new vehicle was, and how it would be used."<sup>363</sup>

The question naturally arises whether consumers were provided with enough information with which to make a decision. If they were not, the case resembles the infamous Ford Pinto litigation, where Ford higher-ups knew, but deliberately declined to make public, that the

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358. Other cars have also been "accused" of a similar propensity to roll over. See *Volkswagen v. Marinelli*, 628 So. 2d 378 (Ala. 1993), in which the court upheld the jury's finding that the Volkswagen "Thing" was defectively designed because of its propensity to roll over.

359. *Kenneally v. Suzuki Motor Co.*, 1994 U.S. Dist. LEXIS 1355 (S.D.N.Y. Feb. 10, 1994).

360. Warren Brown, *NHTSA Employees Criticize Center for Auto Safety's Tactics*, WASH. POST, Sept. 21, 1989.

361. Bill Rankin, *Suzuki Lawyers Join Samurai in Hot Seat*, ATLANTA CONST., Apr. 16, 1993, at D1.

362. One crucial document was described and quoted in *Malautea v. Suzuki Motor Co.*, 987 F.2d 1536, 1541 (11th Cir. 1993). The court in *Malautea* upheld the trial judge's severe sanctions by entering a default judgment against Suzuki on the issue of liability because of abuses during the discovery process. Because of one such abuse, the document discussed above had to be obtained from General Motors, not from Suzuki.

363. Warren Brown, *The Samurai is Superior but Still in Court*, WASH. POST, Apr. 1, 1988, at N54.



Pinto had a propensity to explode in a rear-end collision. In such cases, punitive as well as compensatory damages are appropriate, and were properly imposed.<sup>364</sup> In the Samurai case, enough "information" might come from the appearance of the vehicle itself. However, there is a large difference between a latent defect, like a misplaced steering column or an exploding gas tank, and a small utility vehicle that might be said to disclose its own problems.

This last possibility is the most troubling, as it forces a choice between the somewhat-informed consumer and the manufacturer that, at least to an extent, is fulfilling a consumer-fueled desire. Reduced to essentials, the question is: To what extent, if any, should the consumer be able to bargain away personal safety? The presence on the market of motorcycles, for example, suggests that consumer preference and the attendant manufacturing response are given some weight. But how much?

Before answering this question, let us consider one more alleged automobile defect—airbags. Although the technology for these has been available for more than twenty years,<sup>365</sup> they have been widely available in vehicles only since model year 1992.<sup>366</sup> Since the late 1980s, cases have been brought in which injured plaintiffs involved in front-end collisions have argued that air bags would have prevented or reduced their injuries.<sup>367</sup>

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364. See *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 360 (Cal. Ct. App. 1981).

365. For a useful treatment of this issue, see Stephen D. Sugarman, *Nader's Failures?*, 80 CAL. L. REV. 289 (1992) (reviewing JERRY L. MASHAW & DAVID L. HARFIS, *THE STRUGGLE FOR AUTO SAFETY* (1990)). The technology has been available at least since the early 1970s. *Id.* at 295.

366. *Id.* at 291. Current federal regulations require air bags (or "inflatable restraint systems") for both front seat passengers in 95% of the autos produced by each manufacturer between September 1, 1996 and September 1, 1997, 49 C.F.R. § 571.208 4.1.5.2.1 (*as amended* Sept. 2, 1993); after that, they are to be required in all passenger cars. 49 C.F.R. § 571.208 4.1.5.3 (1993).

367. See, e.g., *Pokorny v. Ford Motor Co.*, 902 F.2d 1116 (3d Cir. 1990); *Wood v. General Motors Corp.*, 865 F.2d 395 (1st Cir. 1988); *Gingold v. Audi-NSU-Auto Union, A.G.*, 567 A.2d 312 (Pa. Super. Ct. 1989). An interesting twist on the air bag defect issue is presented by *Bresnahan v. Chrysler Corp.*, No. BO72243, 1995 Cal. Ct. App. LEXIS 208, in which the court directed the trial court to allow plaintiff to proceed on a consumer expectation theory where the allegedly defective design was an improperly placed airbag. When the bag inflated upon impact, plaintiff's left arm and hand were forced upward into the windshield, and her elbow was driven into the windshield's side pillar, fracturing it. Her argument was that the air bag was defectively placed "in conjunction . . . with the windshield." *Id.* at \*2.

The decisions thus far have addressed whether the claims are preempted by the National Traffic and Motor Vehicle Safety Act.<sup>368</sup> Pursuant to that Act, the Administrator of the National Highway Traffic Safety Administration has issued an ever-changing battery of regulations, beginning in 1967, to deal with crash protection. What has ensued is a postmodern update of Dickens.<sup>369</sup> In short, passive restraint, of which air bags are generally considered the most effective means, was originally contemplated as a requirement for the 1976 model year, but is not to be fully implemented until 1998.<sup>370</sup>

The tortured history of the passive restraint requirement, along with the system's now universally recognized desirability, bleeds the force from MUPLA's presumption of nondefectiveness where governmental standards are followed.<sup>371</sup> But the central question still needs an answer: Should autos without airbags be considered defective?

The beginning of an answer can be found by taking the Samurai, the motorcycle, and the cars without airbags together. Taking the simplest case first: Motorcycles should not be considered defective simply because they are less safe than cars. Consumers know of the relative risk of injury and have an alternative. Moreover, it would probably be impossible to design them to be as safe as cars, at least at reasonable cost or without removing what attracts riders to them in the first place.

As to the other two cases, only the full development of a record during litigation can establish the crucial facts. In cases involving

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368. See, e.g., *Pokorny*, 902 F.2d at 1116; *Wood*, 865 F.2d at 395; *Gingold*, 567 A.2d at 312; *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438, 1446 (10th Cir. 1993) (collecting cases on both sides of the question).

369. I refer here to *Jarndyce v. Jarndyce*, a contested will case that ultimately ended when, after many years of procedural confusion and delay, the estate in question had been entirely consumed by lawyers' fees. CHARLES DICKENS, *BLEAK HOUSE* (Norman Page ed., Penguin Books 1971) (1853).

370. For a synopsis of this saga, see *Wood v. General Motors Corp.*, 673 F. Supp. 1103, 1111-12 (D. Mass. 1987). The Administration's repeated rescission of the implementation date, at one point rejected by the Supreme Court as arbitrary and capricious, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983), speaks more eloquently about the limitations of the regulatory process than any law review article. See also James S. Kunen, *Comment: Rats*, *NEW YORKER*, Mar. 6, 1995, at 8 ("[T]he regulatory process is not known for breakneck speed . . . . The National Highway Traffic Safety Administration . . . issued a standard in 1971 requiring passive restraints in passenger cars as of January, 1972. After petitions for review, court challenges, and political interventions of every sort, the standard is now set to kick in with the 1998 model year.").

371. MUPLA, *supra* note 1, § 10S. See *supra* subpart IV.B.1(c). One might ask whether this is even such a case, since there were no mandatory regulations concerning airbags.

early purchasers and users of the Samurai, for example, the consumer expectation test might well dictate a finding of defectiveness, as the uninformed consumer would "reasonably expect" the vehicles not to roll over as easily as they do.<sup>372</sup> For vehicles purchased later, or for those used after the problem became widely known,<sup>373</sup> it might seem that reliance on consumer expectation analysis would doom the plaintiff.

Yet here, as with airbags, we find cases where the risk-utility analysis might be used profitably in service of the consumer expectation test. If it turned out that the Samurai could have been made more stable at a low cost, the consumer might expect (or be deemed to expect) such expenditure to be made.<sup>374</sup> But the plaintiff might trip over the fact that safer substitutes, especially for everyday driving, are readily available—at least some at the same cost.

As Professor Shapo pointed out generally twenty years ago,<sup>375</sup> attention should be given to the complex cluster of messages that automobile manufacturers generate in order to induce confidence in, and thereby sales to, the consuming public. Thus, a manufacturer that emphasized the safety of a particular model should be called to account when that model proves less safe than others.

The stronger case, then, is with the airbag, since no safer substitute was available at the time the injuries occurred. Absent a market choice,<sup>376</sup> the consumer expectation test—or, the safety "the consumer is *entitled* to expect"—should be stated roughly as follows:

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372. Directive, *supra* note 3, art. 6. The conclusion here is necessarily qualified because the language of the Directive, the "presentation of the product," is an important circumstance to consider in determining defectiveness. A jury's finding that such small vehicles are prone to rolling over might pose problems for a purchaser under this test.

373. The Directive speaks to the issue, listing "the time when the product was put into circulation" as one determinant of defectiveness *vel non*. *Id.* art. 6, § 1(c).

374. MUPLA, *supra* note 1, § 104(B)(2)(a)-(e) lists some of the factors to be considered in making this risk-utility decision.

375. See generally Shapo, *supra* note 11.

376. In *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 37 (1983), the Supreme Court noted that the Secretary of Transportation had rescinded the pending passive restraint requirement because of perceived public hostility to the requirement. Even if that observation were correct, at least some consumers would have valued safety over cost. Indeed, some air bags were available early on. Between 1972 and 1976, General Motors, Ford, and Volvo produced 12,000 cars that offered optional air bags. Frank Waters, *Air Bag Litigation: Plaintiffs, Start Your Engines*, 13 PEPP. L. REV. 1063, 1068-69 & n.40 (1986). Was this limited experiment a financial failure? General Motors claimed poor success in selling the bags, yet all of its cars produced with the systems were sold. *Id.* at 1066. In any case, the industry's perception of consumer reluctance meant air bags were not again available until the mid-1980s, and then only on some Mercedes-Benz models. *Id.* at 1068. The device did not become standard equipment until 1992.

Given the readily available technology for airbags during the past two decades, has the consumer's reasonable expectation of safety been fulfilled? This question is painfully poignant here, as it is sadly evident that the NHTSA failed to fulfill its duty to protect auto occupants.

Deprived of that protection, should the injured consumer be compelled to absorb the cost? On the contrary, a powerful argument is at hand for judicial regulation in such a case. Given the obvious and relatively cheap safety advantage afforded by airbags—or, at least, passive shoulder restraints—administrative inaction invites the court to perform its role of spurring the legislative branch to act. To put the question rhetorically: Should the courts stand to one side when, by the NHTSA's own 1977 estimate, passive restraint systems could have prevented some 12,000 deaths and 100,000 injuries annually?<sup>377</sup>

### C. *Defective Products in the Workplace*

Consider the following examples of injuries incurred in the workplace:

(1) A woman's hand is mutilated when entangled in a grain elevator, from which the gear guard had been removed.<sup>378</sup>

(2) Despite a flurry of warnings from a company succeeding the manufacturer of a press brake, the hand of an untrained young worker was severed when he reached into the machine to pull a metal sheet towards himself. Ownership of the machine had changed several times between initial purchase and injury.<sup>379</sup>

(3) The superstructure of a crane strikes a man and seriously injures him; the danger is "open and obvious."<sup>380</sup>

(4) Pinned at the neck by an overturned forklift, plaintiff suffers serious brain damage. The forklift had ridden on a mechanical dockboard which employed a unique design, materially dangerous in one important respect, but available with an optional safeguard to compensate for that danger.<sup>381</sup>

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377. Waters, *supra* note 376, at 1064-65.

378. Fell v. Kewanee Farm Equip. Co., 457 N.W.2d 911, 913 (Iowa 1990).

379. Seeley v. Cincinnati Shaper Co., 606 A.2d 378, 380-82 (N.J. Super. Ct. App. Div. 1992).

380. Armentrout v. FMC Corp., 842 P.2d 175, 178-S1 (Colo. 1992).

381. Bilotta v. Kelley Co., 346 N.W.2d 616 (Minn. 1984). The optional safety device was not selected by the purchaser, whose identity was not clear in the decision.

(5) Finally, a huge class of workers claims injury resulting from prolonged exposure to asbestos in the workplace.<sup>382</sup>

As the above examples suggest, product-related workplace injuries exhibit many of the same variations as harms caused by general consumer products, but are complicated by the setting in which they arise. In addition to the chain of product distribution typically associated with consumer goods, these cases must often take into account the conduct of another responsible intermediary, the employer. The cases cited above reveal that the employer's engagement with the injuring product may be substantial and may be relevant to deciding whether the employee's injury was due to a defect or to employer conduct. Further, although the life expectancy of a product is not strictly related to the setting in which it is used, the generally long life and frequent resale of industrial machinery threatens to render opaque the already turbid issue of whether the injuring product had passed its useful safe life. The present subsection sketches out some thoughts on approaching workplace defect issues. My bases are, as always, the Directive and MUPLA.

While making no specific reference to cases arising in the workplace setting, the Directive seems to foreclose the possibility that a worker's compensation scheme in a member state could reduce the injured consumer's recovery against the producer.<sup>383</sup> In a case involving both product defect and employer misconduct, as by modifying a product in a dangerous way,<sup>384</sup> or by failing to pass on a manufac-

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382. See, e.g., *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156 (4th Cir. 1986) (affirming directed verdict in favor of asbestos manufacturers, finding that plaintiff had not established causation); *In re Hawaii Fed. Asbestos Cases*, 665 F. Supp. 1454 (D. Haw. 1986) (granting plaintiff's motion to exclude state of the art defense as it applied to strict liability claim); *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633 (Md. 1992) (interpreting Restatement (Second) of Torts § 402A cmt. j (1964) as creating a state of the art defense); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 546 (N.J. 1982) (not permitting defendant to argue that asbestos installation was considered safe at the time plaintiffs were exposed, rejecting state of the art defense). For a more complete listing, see Charles C. Marrel, Annotation, *Strict Products Liability: Liability for Failure to Warn as Dependent on Defendant's Knowledge of Danger*, 33 A.L.R. 4th 368 (1984).

383. Directive, *supra* note 3, art. 13. By the terms of Article 13, liability might be supplemented by an existing worker's compensation scheme; for example, a member state's other protections for injured consumers are not affected by the Directive. However, reducing the producer's liability would defy the Directive's universal goal of increasing consumer protection, render superfluous the specifically permissible derogations from strict liability set forth in Article 15, and contravene Article 8, paragraph 1.

384. See, e.g., *Fell v. Kewane Farm Equip. Co.*, 457 N.W.2d 911, 916 (Iowa 1990); *Robinson v. Reed-Prentice*, 403 N.E.2d 440 (N.Y. 1980).

turer's warning,<sup>385</sup> Article 8 announces that "[t]he liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party." The producer might, depending on the law of employer liability within the jurisdiction, have "contribution or recourse"<sup>386</sup> against an employer, but the victim's recovery against the producer would be unimpeded.<sup>387</sup>

MUPLA, by contrast, expressly reduces the claimant's award in the product liability suit by "the amount paid as Worker Compensation benefits for the . . . injury plus the present value of all future Worker Compensation benefits payable for the same injury under the . . . statute."<sup>388</sup> The statute goes on to deny the employer any right to subrogation against a product manufacturer where workers' compensation benefits are paid out to an injured employee, unless the employer has been able to wrest an express agreement of indemnity from the seller.<sup>389</sup> Thus, the first subsection addresses the suit brought outside of the workers' compensation statute,<sup>390</sup> while the second considers the procedure to be followed where no suit is brought.

The analysis accompanying section 114 makes an elaborate argument favoring its approach, zeroing in on a tension inherent in product injury in the workplace cases. On the one hand, philosophical

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385. The point is somewhat tricky because the product can be considered defective by reason of inadequate warning if, and only if, the court finds that the manufacturer has a duty to take reasonable steps to warn the ultimate user (here, the employee). In a jurisdiction adopting that approach, both the producer and the employer could be liable, although a member state's own worker compensation scheme might supersede the employer's responsibility. An example of a case adopting this approach is *Oman v. Johns-Manville Corp.*, 764 F.2d 224 (4th Cir. 1985), *cert. denied*, 474 U.S. 970 (1985). The other approach is to regard communication of an adequate warning to the employer as legally sufficient. *See, e.g., Rusin v. Glendale Optical Co.*, 805 F.2d 650 (6th Cir. 1986). A thorough discussion of the cases appears in Kenneth M. Willner, Note, *Failures to Warn and the Sophisticated User Defense*, 74 VA. L. REV. 579 (1988).

386. Directive, *supra* note 3, art. 8, para. 1.

387. Compare *id.* art. 8, para. 1 (prohibiting a reduction of liability where injury is due, in part, to the action of a third party) with *id.* para. 2, (where the plaintiff's negligence contributes to the injury the producer's liability "may be reduced or disallowed"). However, one cannot completely ignore the final clause of Article 8, paragraph 2 which reduces recovery traceable to the fault of "any person for whom the injured person is responsible." If a national court concluded that employers were, for purposes of this section, responsible for their employees, recovery might be reduced. I suspect the answer would mostly depend on the worker's compensation law in effect in the jurisdiction.

388. MUPLA, *supra* note 1, § 114(A).

389. *Id.* § 114(B).

390. Section § 114(C) follows up on § 114(A), allowing the seller to bring an action for reduction of the judgment when the suit is concluded before the inevitable workers' compensation proceeding has ended. If an award has already been made, the seller is entitled to "recoupment from the employer." *Id.* § 114(C).

commitment to workers' compensation as the exclusive remedy for workplace injuries argues against a complete contribution claim by seller against employer. If that course were permitted, the employer might pay greater damages than would be statutorily permissible under workers' compensation.<sup>391</sup> On the other hand, disallowing contribution against the employer might leave the seller to make full reparation, "despite the possibly greater responsibility of the employer."<sup>392</sup>

The Directive's approach, although leaving workers' compensation law out of the statutory scheme, is preferable. MUPLA, concerned with the transaction costs attendant to dissecting and assigning liability in the setting of defective workplace products, effectively allows employer contribution to reduce the liability of product manufacturers even if they may be fully responsible for causing injury. Such would be the case with asbestos, for example, assuming that the manufacturer would be liable in the first place. Allowing full recovery against the seller could permit the injured worker to obtain more than full recovery by way of full tort damages in the suit against the manufacturer, plus workers' compensation damages.

But this problem may be more seeming than real. First, it may be a mistake to assume that such outsized recovery must be avoided. Plaintiffs routinely receive a "windfall" of sorts when punitive damages are permitted; allowing such damages to go directly to plaintiff is thought, in part, to provide incentive for the plaintiff to bring suit in cases where such a course might not otherwise promise substantial recovery.<sup>393</sup> If it is nonetheless deemed wise to prevent the "windfall" recovery that could ensue under my suggested approach, it would be better to cede the spillover recovery to some third party, such as an eleemosynary institution of the manufacturer's choice.<sup>394</sup>

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391. *Id.* § 114 (accompanying analysis).

392. *Id.* The analysis accompanying § 114 discusses the approaches considered but discarded, and notes that its approach is "based, in substantial part, on a proposal developed by the American Insurance Association [that] has also been incorporated in the 'National Workers Compensation Standards Act of 1979' . . . and 'Standards for State Product Liability Tort Litigation Act'." *Id.*

393. *See, e.g.,* *Alcorn v. Mitchell*, 63 Ill. 553 (1872) (plaintiff spat upon in the courtroom; court upheld award of \$1000 in punitive damages, noting that the "law . . . should afford substantial protection against such outrages, in the way of liberal damages," so as to allow the plaintiff to participate in the preservation of public order).

394. I have long thought that such a creative approach would have prevented some of the outrage that followed the result in *Katko v. Briney*, 183 N.W.2d 657 (Iowa 1971). It was not seriously questioned that plaintiff, who was seriously injured by a rigged gun while breaking into defendant's storehouse, should receive compensatory damages, but the dis-

As the drafters of MUPLA point out, the real problem domestically is that there has been no integration of workers' compensation and product liability law.<sup>395</sup> Until this is achieved, proper allocation of responsibility between the parties may in fact result in excessive recovery for the plaintiff, because the worker compensation law will require payment by the employer in every case. The preferred approach would be to assess the responsibility of all parties in the chain of a product's manufacture, distribution, sale, resale, and use. By leaving the employer out of the mix, the Directive allows allocation to take place as it would in a typical case. MUPLA, hemmed in by the reality of the worker compensation law, gropes unsuccessfully for an equitable compromise.

Several factors may combine to render the achievement of a just result especially difficult in workplace cases, even apart from the statutory worker's compensation problem. The case of *Seeley v. Cincinnati Shaper Co.*<sup>396</sup> provides a convenient stalking horse for assessing how courts weave through complex legal and factual issues on their way to a decision, as well as a means for grading the performance of both the Directive and MUPLA in challenging workplace litigation.

The offending machine in *Seeley* was a press brake, which severed the plaintiff's hand when he reached into it to recover an ill-positioned metal sheet. The machine had been manufactured in 1966 with a point-of-operation guard.<sup>397</sup> As manufactured, "the machine not only accepted such a guard, but was inoperable without it."<sup>398</sup> But by the time of plaintiff's injury in 1987, the press brake had been sufficiently modified in other ways that the guard could be, and had been, removed.<sup>399</sup> That removal, however, was not the "fault" of plaintiff's employer because it had purchased the machine after the guard's removal.<sup>400</sup>

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sent expressed outrage over forcing the defendants to pay punitive damages to the plaintiff under these circumstances. *Id.* at 663 (Larson, J., dissenting).

395. MUPLA, *supra* note 1, § 114 (accompanying analysis) (preferring that the worker compensation law be the sole source of recovery in product-injury cases, but only if worker compensation were achieved: "A model product liability law, however, is an inappropriate vehicle for making alterations of that dimension in Worker Compensation law.").

396. 606 A.2d 378 (N.J. Super. Ct. App. Div. 1992).

397. Since the complaint acknowledged that such a device, even if present, might not have prevented plaintiff's injury, it is somewhat puzzling why the court discussed this point at length. As it turns out, the more serious problem cited by plaintiff was the lack of a "universal" guard.

398. *Seeley*, 604 A.2d at 379.

399. *Id.* at 380.

400. *Id.*



The case is rich in further complications, only some of which were material to the result. First, ownership of the machine had changed hands several times between initial purchase and injury;<sup>401</sup> second, the plaintiff had been given only fifteen minutes of training by the employer before being sent to use the press brake;<sup>402</sup> third, although the machine had been modified in many ways during the twenty-plus years between manufacture and injury, the modifications were not relevant to the putative defect in design, which was a failure to include a universal guard.<sup>403</sup>

The final set of important facts relates to the postsale conduct of defendant, a successor to the manufacturer. At first, Cincinnati did an exemplary job of keeping up with its machine,<sup>404</sup> but lost track of it after a few years, having received no further requests for maintenance. Shortly after plaintiff's employer purchased the press brake, it contacted Cincinnati and requested operations manuals, thereby reestablishing communication.<sup>405</sup> The defendant sent a letter urging the employer to consider changes in the safety climate that might require "updating,"<sup>406</sup> and enclosed several other materials. The court set forth the substance of these materials in detail. In sum, they informed the employer of the necessity of meeting relevant safety standards,<sup>407</sup> of the dangers of placing one's hands into the point-of-operation, and of other suggested safeguards, including maintenance and the proper use of safety signs, which were also included with the materials.

Finally, defendant sent an agent to make a service call on plaintiff's employer. Once there, he concluded that the large-scale modifications to the press brake made it an unsuitable candidate for service. He neither saw the machine in operation nor believed he was making a "safety visit."<sup>408</sup>

One of the most trying tasks for a court in such complex cases is to decide which issues are relevant to its decision. Here, for example, the court correctly concluded that the modification of the machine, although extensive, was ultimately not relevant to plaintiff's design defect allegation. Although several (extraneous) pages were spent on

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401. *Id.*

402. *Id.* at 379.

403. *Id.*

404. *Id.* at 380.

405. *Id.*

406. *Id.*

407. These standards were set forth for the industry by the American National Standards Institute (ANSI). *Id.* at 381.

408. *Id.* at 382-83.

the issue of the point-of-operation guard, the decision recognized that plaintiff claimed a failure to include a universal guard that would have presumably prevented his injury.<sup>409</sup> Thus, the allegation that the safety devices had been removed was dropped from consideration. This approach is consonant with both the Directive and MUPLA, and fits well with both existing case law and basic tenets of causation. As long as the modification does not affect what actually happened to the plaintiff, it should be irrelevant.

With the troubling issue of safety devices thus put aside, the court was left to wrangle with a welter of other issues. Indeed, perhaps the purest lesson to be learned is that no statute, directive, or regulation can sufficiently anticipate the endless range of product problems to provide courts with answers. The central question, around which all others orbited, was whether the press brake was "defective." Yet, the court in *Seeley* would have found little assistance from general statutory invocations to consider the "presentation of the product"—or "the use to which it could reasonably be expected [it] would be put"<sup>410</sup>—or whether "the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms outweighed the burden on the manufacturer to design a product that would have prevented those harms."<sup>411</sup> All that could be said is that the case might assume a different *aspect* to the court, depending on whether the defect is to be assessed from the perspective of the injured user (a better word than "consumer" in the workplace setting) based on product presentation, or from the point of view of the manufacturer, weighing risks against benefits.

Nevertheless, the more specific provisions in both the Directive and MUPLA might have furnished assistance to the *Seeley* court in slogging through some of the case's complexities. Had modification of the point-of-operation guard been causally relevant, for example, the Directive would have allowed liability to persist if such could have been "anticipated" by the producer;<sup>412</sup> in this case, since the machine, as manufactured, was "inoperable" without the point guard, liability would not seem proper. Yet, since the presentation includes warnings—and noting the economics of the workplace—we might want to require an admonition to forego modification that might allow removal of the guard, which in turn might lead to injury. Liability under

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409. *Id.* at 379.

410. Directive, *supra* note 3, art. 6, § 1.

411. MUPLA, *supra* note 1, § 104(B)(1).

412. Directive, *supra* note 3, art. 6, para. 1(b).

MUPLA could follow a similar pattern; although modifications generally exculpate producers,<sup>413</sup> it might be possible to bring the modification within the exception for reasonably expected conduct, if the manufacturer should have warned against doing so.<sup>414</sup>

The case might also test judicial commitment to the restrictions on recovery imposed by statutes of limitation and repose. The machine was manufactured and sold in 1966, but did not injure the plaintiff until 1987, thus invoking absolute manufacturer immunity under the Directive's Article 11,<sup>415</sup> while triggering the less absolutely protective cloak of a presumption rebuttable only by "clear and convincing evidence" under MUPLA.<sup>416</sup> In this case, such "clear and convincing evidence" might be adduced through a showing that many of these machines were still in use, or, as in this case, that the successor to the manufacturer sent a representative to instruct the employer on the proper use of the machine, thereby creating an implied representation that it could still be used safely.

#### *D. Liability for the Sale of Injury-Causing Pharmaceuticals*

This final topic has been introduced earlier in this Article.<sup>417</sup> My goal here is to emphasize the gains in justice that follow from adopting the Directive's emphasis on the consumer's expectation in these cases, and in any cases that might be said to involve "unavoidably unsafe" products. Indeed, insofar as the Act inadvertently allows the consumer's expectation to creep into the analysis at all, it inches, albeit inconsistently, toward a more just result. For the most part, though, the Act abandons focus on the consumer in favor of the manufacturer's balancing of risks and utilities, and thereby falls short of supplying suitable protection to the product-injured consumer.

One might begin this analysis by asking why drugs are singled out for special treatment. This unusual status, which can be traced back at least as far as comment k to Restatement (Second) of Torts, section 402A, stems from a recognition that drugs are likelier than other products to be "unavoidably unsafe." Of course, the category of unavoidably unsafe products is hardly restricted to drugs; rather, because

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413. MUPLA, *supra* note 1, § 102(D).

414. *See id.* § 102(D)(2)(d).

415. *See supra* notes 206-10 and accompanying text.

416. *See supra* notes 316-33, discussing the limitations provisions of MUPLA. As mentioned there, MUPLA at least avoids the flat bar of statutes of repose in effect in many states.

417. *See supra* subparts III.B.4 & IV.B.1(c).

they are often necessary for health and well-being, it is perhaps permissible to allow them to bear a higher level of inherent risk than we would tolerate for other products. Thus arises the conclusion that such products are culpably defective only when unavoidably unsafe.

Domestic courts have struggled both to determine whether a product is unavoidably unsafe,<sup>418</sup> and, if so, whether that information was sufficiently communicated to its user.<sup>419</sup> Although most drug cases are analyzed as involving an "unavoidably unsafe" product, some courts have recognized that such treatment is not always warranted.<sup>420</sup> Once the determination of unavoidable "unsafety" has been made, though, the inquiry shifts to the adequacy of warning.

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418. A threshold question that has pestered courts is whether *all* prescription drugs should be subject to the "unavoidably unsafe" defense, or whether the doctrine should only apply "when it is shown that [the] product is incapable of being made safe given the present state of human knowledge but possesses such a high degree of social need so that its use is warranted, provided warnings are adequate." *Hill v. Searle Lab.*, 584 F.2d 1064, 1068 (8th Cir. 1989) (citing cases on both sides of the question). The *Hill* court took the latter view, and then proceeded to find that the intrauterine device under attack did not qualify for comment k treatment, since "alternative means of birth control are available and [the manufacturer had] made no showing that . . . IUDs in general . . . are exceptionally beneficial to society." *Id.* at 1069-70. The court also noted that the drafters of comment k considered granting "a blanket exception" to strict liability for prescription drugs, but that the "proposal was defeated." *Id.* at 1069, citing 38 ALI PROC. 19, 90-93 (1961). The court also noted that the example given in the text of comment k—the Pasteur rabies vaccine—"suggests that only special products, those with exceptional social need, fall within" the exception's reach. *Id.* at 1069. In accord with this reasoning is *Patten v. Lederle Lab.*, 676 F. Supp. 233 (D. Utah 1987) (involving defendant's motion for instruction on the DPT vaccine). Even under a case-by-case approach, though, courts have assumed that some products plainly qualify for "unavoidably unsafe" status. *See, e.g., Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1274 (5th Cir. 1974) (oral polio vaccine was justifiably marketed despite the "minuscule" danger of contracting polio); *Harwell v. American Medical Sys., Inc.*, 803 F. Supp. 1287 (M.D. Tenn. 1992) (court concludes, without analysis, that a penile prosthesis is unavoidably unsafe).

419. Thus, given the usual determination of unavoidable danger, the warning issue pushes to the fore in the vaccine cases. *See, e.g., Reyes v. Wyeth Lab.*, 498 F.2d at 1275-73 (despite vaccine's prescription drug status, manufacturer should have known that product "would not be administered as a prescription drug, and therefore was required to warn foreseeable users"); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1498-99 (D. Kan. 1987) (manufacturer's motion for summary judgment on the warning issue denied since the issue was factual, and reasonable people could disagree as to whether manufacturer's warning was adequate); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324-26 (Kan. 1986) (warning adequate as a matter of law).

420. The clearest set of cases in which the product should not be treated as "unavoidably unsafe" is where a particular batch of an otherwise safe drug is defective. *Gottsdanker v. Cutter Lab.*, 6 Cal. Rptr. 320 (Cal. Dist. Ct. App. 1960) (Salk polio vaccine; virus not killed as others were). Or, a product may be unsafe by comparison to available, safer alternatives. This was particularly the case in *Brochu v. Ortho Pharmaceutical Co.*, 642 F.2d 652 (1st Cir. 1981), in which the court found that strict liability was the proper theory

Read properly, the Directive's approach to the difficult issue of injury-causing pharmaceuticals encourages courts to continue to ask these two questions: Was the drug designed with reasonable safety, from the consumer's perspective; and, if some level of unsafety is unavoidable, were adequate warnings given? Recall that the main question asked under the Directive is whether the product is "defective,"<sup>421</sup> and that answering this question requires examination of the product's presentation, including, presumably, both design and warnings.<sup>422</sup> Thus, a valuable drug such as insulin would not ordinarily be deemed defective so long as the consumer's decision to use the drug is properly informed by disclosure of material<sup>423</sup> side effects. Yet it would also be possible for an injured user of the drug to argue that insulin could have been made safer. A particular dosage of the drug might be tainted, thereby betraying the consumer's expectation in the clearest way. Or, less likely, the drug might not have been adequately tested for possible adverse side effects. As a related matter, safer alternatives might exist or be technologically feasible. Thus, the Directive's approach vindicates the consumer's expectations that the manufacturer has taken reasonable steps for her safety throughout the course of pharmaceutical research, development, and marketing.<sup>424</sup>

MUPLA, by contrast, inconsistently values the consumer's expectation and leans more heavily on a risk-utility calculus that seems particularly inapposite where warnings are involved. Section 104(C) contains the most direct focus on consumer expectation, but is of small comfort, as it concerns the *denial* of recovery; liability is precluded for failure to "warn about dangers that are obvious."<sup>425</sup> Other-

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where a contraceptive pill contained 100 milligrams of estrogen, even though a fully effective dosage was only 50 milligrams, presenting a lower risk.

421. Directive, *supra* note 3, art. 6.

422. See *supra* subpart III.B.2.

423. The adjective is used to restrict recovery to those cases in which a reasonable user of the drug, presumably a diabetic, would attach importance to the side effect in question. Given the great value, perhaps necessity, of insulin, only quite serious side effects might call forth a duty of disclosure. Cf. *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir. 1972) (consent is only "informed" when the "[p]atient possesses enough information to enable an intelligent choice . . . [a]ll risks potentially affecting the decision must be unmasked.").

424. Recall, too, that under the Directive's definition of state of the art defense, or what has been called "development risks," knowledge of a problem is sufficient to impose liability—presumably for failure to warn—even if the current state of science and technology do not permit the problem's cure. Article 7 asks whether "the state of . . . knowledge . . . was . . . such as to enable the existence of the defect to be discovered." Directive, *supra* note 3, art. 7.

425. MUPLA, *supra* note 1, § 104(C)(4).

wise, the overarching philosophy is to impose liability where the "manufacturer should and could have provided . . . warnings . . . ." <sup>426</sup> Standing alone, this language admits an interpretation that values reasonable consumer expectation in deciding whether warnings "should and could" have been supplied. And, MUPLA at least makes noises in that direction by asking whether the manufacturer was able to "anticipate that the likely user would be aware of any danger" <sup>427</sup> and "how clear and conspicuous were [the] warnings?" <sup>428</sup>

These understandable concerns uncover the powerful pull of a liability regime that honors the consumer's informed choice, and that mulcts sellers who, having the opportunity, fail to engage the consumer in the making of decisions crucial to his physical and emotional well-being. Perhaps this acknowledgment shows that issues of warning quite patently involve a dialogue between seller and buyer: "This is as safe as I can, or am financially willing, to make this product. It contains hazards, which I'm enumerating. Do you still want it?" The buyer can answer yes or no only if the information is presented in this sort of straightforward way.

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426. *Id.* § 104(C)(1).

427. *Id.* § 104(2). This limitation on liability has been consistently recognized by the courts. *See, e.g.,* *Martinez v. Dixie Carriers, Inc.*, 529 F.2d 457, 465 (5th Cir. 1976) (worker died from exposure to toxic fumes from petrochemical product; district court's finding of liability reversed because of limited market into which defendant had sold product, a market in which it "could reasonably anticipate that only a professional familiar with the precautions necessary for safe handling of benzene and similar petrochemical substances would come in contact with or otherwise handle the [product] . . ."); *Jamieson v. Woodward & Lothrop*, 247 F.2d 23, 28 (D.C. Cir. 1957) (no duty to warn purchaser of elastic exerciser who was injured when the device "snapped back" and struck her in the eye since "small boys know . . . that a rubber band is elastic and when stretched will, when released, return to its original length with some degree of force"); *Poland v. Beaird-Poulan*, 483 F. Supp. 1256, 1264-65 (W.D. La. 1980) (plaintiff, an experienced user of chain saws, did not need to be warned that chain saw, if not properly maintained, could "kick back" and cause injury).

428. MUPLA, *supra* note 1, § 104(4). For cases finding no duty to warn of dangers that are clearly and conspicuously identified, see *Cotton v. Buckeye Gas Prod. Co.*, 840 F.2d 935, 937-38 (D.C. Cir. 1988) (clear and conspicuous label warned that propane cylinder's contents were "flammable" and should not be used or stored in "living areas"); *Higgins v. E.I. DuPont de Nemours & Co.*, 671 F. Supp. 1063, 1065-66 (D. Md. 1987) (where paint designated for "industrial use" was accompanied by "clear and conspicuous [label] warnings against the use of the product by amateur painters," firefighters who claimed injury from fumes lost on summary judgment). *But cf. Toy Mfrs. Ass'n, Inc. v. Blumenthal*, 986 F.2d 615, 619 (2d Cir. 1992) (denying manufacturer's motion for declaratory judgment that federal law preempted a state statute prohibiting the sale of "any toy or other article marketed or determined to be for the use of children . . . which does not bear 'a conspicuous warning label that clearly and conspicuously communicates that the contents contain small parts'" (quoting CONN. GEN. STAT. § 21a-337, as amended by 1992 Conn. Pub. Acts No. 92-127, § 1, and 1992 Conn. Pub. Act [May Session] No. 92-11, § 57)).

Yet this "lapse" into consumer expectation language is somewhat overborne by the MUPLA's insistence, again in section 104, that liability be assessed from the manufacturer's point of view: "Was [the manufacturer] able to know of the product's danger?" and "How feasible and practical would it have been to provide warnings?"<sup>429</sup> This reading is bolstered by reference to section 106, which restricts liability for unavoidably dangerous products to cases where the "seller knew or had reason to know of the [unavoidably dangerous] aspect" of the product, and was therefore unreasonable in failing to warn, or—in rare cases—in selling the product at all.<sup>430</sup>

Again, the very word "warning" suggests consumer involvement, but the skewed focus of MUPLA seems to drive courts back toward the risk-utility calculus. A few examples will show that the focus makes a difference in a subset of drug cases, and that in those instances, the consumer expectation test is more likely to achieve a fair outcome.

It is perhaps useful to begin with those cases in which there is no difference in result under either a consumer expectation or a risk-utility test. In most cases, when a product is sold over-the-counter, sufficient experience with the properties of its ingredients enables a clear, full warning of material hazards. Thus, where a cold remedy expressly warns of drowsiness, a user who is injured when he falls asleep while driving to work should have no claim. Proper warning in these cases means clear and conspicuous language in the product's packaging, since such drugs are consumed "typically without any intended or actual intervention by a physician."<sup>431</sup>

The chief difference between over-the-counter and prescription drugs—physician involvement in the decision whether and how to take the drug<sup>432</sup>—also suggests a complication in the chain of warn-

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429. MUPLA, *supra* note 1, § 104(C). In the workplace setting, the Act, in adopting a more humane version of the "no duty to warn" rule, nonetheless focuses only on the conduct of the manufacturer, leaving out the expectations of the injured worker. *Id.*

430. *See supra* subpart IV.B.1(c).

431. *Torsiello v. Whitehall Lab.*, 398 A.2d 132, 137 (N.J. Super. Ct. App. Div. 1979).

432. *See* JAMES T. O'REILLY, *FOOD AND DRUG ADMINISTRATION*, § 13.10, at 13-60 (1993). In determining a drug's legal status, among the important questions to ask is whether the drug is dangerous if used "without practitioner supervision . . . . If so, prescription status rather than OTC [over the counter] status is likely . . . ." *Id.* Of course, this determination does not take place in a political vacuum. For a particularly scathing criticism of the process by which drugs move from prescription to over-the-counter status, see Jerry Avorn, *Drug Regulation and Drug Information—Who Should Do What to Whom?* 85 AM. J. PUB. HEALTH 18, 18-19 (1995) (the "eats-through anything medical cost containment movement, . . . consumer activism, the waning clout of physicians, and the zeal of

ings; one that has been the subject of analysis in several decisions. Because of the anticipated conversation between patient and physician, the general rule has been that an adequate warning to the physician discharges the duty to warn as a matter of law.<sup>433</sup> This general rule makes good sense in the majority of prescription drug cases, just as it does in the employment setting.<sup>434</sup> After all, the justification for such indirect warnings is that a physician who is familiar with the medical history of the patient, the suitability of the drug for the health goal to be achieved, and the adverse side effects that may ensue, will engage the patient in a discussion. This exchange would necessarily include warnings more specifically targeted than those generically available in an over-the-counter setting.<sup>435</sup> Under most circumstances, then, directing a warning to the physician would be in harmony with the consumer expectation model of liability.

Yet cases such as *MacDonald v. Ortho Pharmaceutical Corp.*<sup>436</sup> highlight the limitations of steadfast reliance on the physician. In a case involving a stroke caused by ingestion of oral contraceptives, the court took note of the actual circumstances that often surround such prescriptions, and imposed a duty to warn the patient directly.<sup>437</sup> Interestingly, it put forth justifications for this result that are in tension. On the one hand, the court noted that "whereas a patient's involve-

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manufacturers and pharmacists who have found that products with unrestricted availability, even at lower costs, can generate more profits than products with prescription-only status" are factors pushing towards over-the-counter status despite contrary clinical indications).

433. "[T]he prescribing physician acts as a 'learned intermediary' between the manufacturer and the patient, and 'the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty.'" *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69 (Mass. 1984) (quoting *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 529 (Or. 1974), *cert. denied*, 794 U.S. 920 (1985)).

434. The argument is that the employer, knowing the workforce, will typically be better equipped to convey warnings with the proper import.

435. See Avorn, *supra* note 432, at 19 (decrying the inadequacy of warnings from the consumer's perspective when a drug moves to over-the-counter status: "Instructions for use and listings of warnings, adverse effects, and even ingredients, which are scantily presented in microtype on most over-the-counter medications, cannot be expected to help most consumers.").

436. 475 N.E.2d 65, *cert. denied*, 474 U.S. 920 (1985).

437. Although *MacDonald* is probably the best-known example of a court requiring warnings to the consumer in the prescription drug context, it certainly was not the first. See, e.g., *Reyes v. Wyeth Lab.*, 498 F.2d 1269, 1277 (5th Cir. 1974) (duty to warn foreseeable users of the Sabin oral polio vaccine); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981) (where federal and state law mandated warnings and found negligence per se in failing to supply such warnings, failure to directly warn the user of oral contraceptives was actionable).



ment in decision-making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually *actively involved* in the decision . . . and the . . . physician is relegated to a relatively passive role."<sup>438</sup> On the other hand, it remarked that, because the prescription is renewed automatically, the patient "may only seldom have the opportunity to explore her questions and concerns about the medication . . . ." <sup>439</sup>

The first of these observations, to the extent valid, may argue in the other direction: If the woman taking the drug is "actively involved" in her decision, the drug company probably should not be liable when it supplies a proper warning to the physician. If the physician chooses to be "passive," liability is properly assessed against him or her. If rote renewal without further conversation is common, as seems more likely, then the very dialogue that the prescription requirement is supposed to foster is not taking place. Accordingly, manufacturers should be compelled to warn the consumer directly.<sup>440</sup> The FDA's regulations regarding the pill also supported the court's decision, as they were based on findings that users "should, without exception, be furnished with written information telling them of the drug's benefits and risks."<sup>441</sup>

The risk-utility and consumer expectation tests might well come to the same result in this case, but the latter test respects the reality of the exchange between patient and physician. The risk-utility test might exculpate a seller based on some objective determination that direct communication to consumers of the dangers of prescription drugs was "not reasonable." Again, such emphasis does violence to the legitimate expectations of the drug user.

The other case in which the choice of liability theory could be of importance involves experimental drugs, in which the users are, to some extent, human guinea pigs.<sup>442</sup> Vaccines for polio, for example, have not unexpectedly caused some small percentage of the popula-

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438. MacDonald, 475 N.E.2d at 69.

439. *Id.*

440. In MacDonald, the defendant had, in fact, transmitted a warning directly to the patient. Since the jury found that warning inadequate, however, the question whether a warning to the physician sufficed assumed central importance. *Id.* at 70-71.

441. *Id.* at 70.

442. The comparison may be inapt when the user's status is one of choice, presuming full disclosure is made.

tion to contract polio.<sup>443</sup> This risk, however, which is greatest when an effective vaccine is first used—before final safety screening procedures have been established<sup>444</sup>—should be effectively communicated to potential users. Yet MUPLA presumably would not require such a warning, assuming that the risks of infection without the vaccine outweigh the risks of infection by the vaccine.<sup>445</sup> This risk-utility calculus undermines the result in cases such as *Davis v. Wyeth Laboratories, Inc.*,<sup>446</sup> in which the plaintiff was not informed that the Sabin polio vaccine, even when properly administered, carried a one-in-one-million chance of infection. The court's focus on the plaintiff's actual circumstances is instructive. While agreeing that the chances of contracting polio from the vaccine were generally much lower than from not taking it, the court validated the jury's conclusion that the plaintiff's situation might be different because of his age and because "the immediate past history of incidence was extremely low"<sup>447</sup> where he lived. Thus, he might well have decided to forego the vaccination. Translated into consumer expectation language, a reasonable potential user of the vaccine might expect disclosure of the possibility of infection through vaccination, because everyone is not similarly situated.

Of course, the understood requirement for recovery in cases such as *Davis* is that the undisclosed risks are known, though small. Both the Directive and MUPLA assume no liability where the risks are unknown.<sup>448</sup> Under either a risk-utility test or a consumer expectation

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443. This risk is a constant one with vaccines, as vaccinations involve innoculating the subject with the very virus the vaccination seeks to prevent. See Jonas Salk et al., *Noninfectious Poliovirus Vaccine*, in *VACCINES* (Stanley A. Plotkin & Edward A. Mortimer eds., 1994): "The aim of vaccination against polio is to induce immunity to the disease without causing the disease that the vaccine is intended to prevent." *Id.* at 219. Dr. Salk maintains to this day that infection with polio from the killed-cell vaccine that he pioneered was a result of one laboratory's failure to follow approved safety procedures. *Id.* at 209.

444. Dr. Salk himself concedes that the experience of infection by failure to follow approved procedures had the "effect of . . . introduc[ing] a precautionary second . . . step during the inactivation process, although the absence of such a step had not been the cause of the problem." *Id.*

445. Recall that, by the terms of section 104(C)(1), adequacy of warning is assessed by reference to "the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms . . ." MUPLA, *supra* note 1, § 104(c)(1).

446. 399 F.2d 121 (9th Cir. 1968).

447. *Id.* at 130.

448. Directive, *supra* note 3, art. 7(e), (no liability unless "the state of scientific and technical knowledge was . . . such as to enable the existence of the defect to be discovered"); MUPLA, *supra* note 1, § 106(B)(1) (no liability "unless the seller knew or had reason to know of the [unavoidably dangerous] aspect [of the product] . . .")

test, why should a drug manufacturer not be liable for failing to inform the user that the drug is experimental and that it may harbor effects as yet undisclosed? It appears that cases of this sort will largely arise inadvertently, as providers of drugs at the clinical trial stage are usually careful to spell out their ignorance.<sup>449</sup> Where such disclosure is provided, liability should not attach.<sup>450</sup>

While less than clear on this point, the Restatement's language in comment k can be read to afford the decision-maker some leeway in such cases. With experimental drugs, although "there can be no assurance of safety," comment k still imposes the "qualification that [such drugs] are properly prepared and marketed . . . ."<sup>451</sup> Proper marketing might include a warning to the effect that the product's dangers are still a mystery.

## VI. Conclusion

Product liability issues mirror questions found throughout tort law, issues that require continual judicial effort in the "upkeep of the common law."<sup>452</sup> For that reason, legislative enactments choking off liability in whole classes of cases are misguided. As we have seen, both the Directive and MUPLA have generally managed to avoid such a blunderbuss approach, lacing their substantive liability rules

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449. The current, and understandable, rush to bring drugs for combatting the human immunodeficiency virus (HIV) to market furnishes dramatic examples of this sober disclosure. See, e.g., *Informed Consent Form to A Double-Blind, Placebo-Controlled Dose Ranging Study of Salk HIV Immunogen in Incomplete Freund's Adjuvant in Patients with Early Human Immunodeficiency Virus Infection*, at 3 (Mar. 14, 1990) (on file with the author) ("Theoretically, a vaccination of any kind might cause a worsening of my infection with HIV . . . . With any investigational treatment there may be risks involved that are not yet known and are currently unforeseen.").

450. My colleague Barry Furrow has recently argued that drug manufacturers and, where applicable, managed care organizations, should be subject to "absolute strict liability with limited affirmative defenses," such as the fault of the patient or the prescribing physician. Barry R. Furrow, *Enterprise Liability for Bad Outcomes From Drug Therapy: The Doctor, The Hospital, the Pharmacy and the Drug Firm*, 44 *DRAKE L. REV.* (forthcoming Spring 1996). This position probably approximates my own. By valuing the consumer to the extent of dispensing with defenses based on the "reasonableness" of the drug manufacturer's conduct, while allowing defeasement of liability where an affirmative showing of misconduct at some other point in the product's chain can be identified. My only criticism of this position is that its imposition of liability for "bad" patient outcomes begs the question of what, in these cases, is to count as a "bad" outcome. Are even serious side effects from a drug to treat HIV infection necessarily "bad," for example? I believe we can ascertain the meaning of "bad" in specific situations by looking to the consumer's reasonable expectation (under the circumstances) of product performance.

451. *RESTATEMENT (SECOND) OF TORTS* § 402A cmt. k (1977).

452. *Elden v. Sheldon*, 758 P.2d 582, 594 (Cal. 1988) (Broussard, J., dissenting).

with hedges and balances that encourage jural participation and creativity.

Nonetheless, the underlying philosophy of a particular statutory regime sends courts off in a particular direction, and is therefore of signal importance. Because the Directive's consumer expectation and protection model better serves justice in focusing on the communications between the product seller and the (reasonable) plaintiff, it is to that extent preferable to MUPLA's risk-utility calculus, which devalues such expectations.

That said, some refinement of the law is welcome, and MUPLA, at least in its intended effect on the conduct of litigation and in making hard choices on such recurrent problems as the liability of non-manufacturing sellers and on regulatory compliance, has cemented some solutions to issues that had been needlessly fluid. One need not agree with every proposed solution to laud MUPLA's efforts at streamlining product litigation. Indeed, the Directive's principal fault is in failing to deal squarely with such issues. Although such paralysis may be explainable by the importance and difficulty of achieving the central goal of strict product liability, the Directive should be seen as but a modest first step in the greater task that looms. That task is no less than the creation of a consistent body of product law on both sides of the Atlantic, within the limits imposed by the nature of product defect cases.

